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No. 97-615

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1997

TRUSERV CORPORATION, *Petitioner*,

v.

THE PEOPLE OF THE STATE OF CALIFORNIA, EX REL. DANIEL E. LUNGREN, ATTORNEY GENERAL, AND AS YOU SOW, *Respondents*.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

RESPONDENT PEOPLE OF THE STATE OF CALIFORNIA'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

DANIEL E. LUNGREN
Attorney General
RODERICK E. WALSTON
Chief Assistant Attorney General
THEODORA BERGER
Assistant Attorney General
CRAIG C. THOMPSON
EDWARD G. WEIL
SUSAN S. FIERING*
Deputy Attorneys General
(*Counsel of Record)
2101 Webster St., 12th Floor
Oakland, CA 94612-3049
Telephone: (510) 286-3892
Attorneys for Respondent the People of the State of California

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QUESTION PRESENTED

California's Proposition 65 requires that businesses that expose individuals to certain toxic chemicals provide "clear and reasonable" warnings. Warnings may be provided in any of several ways, one of which is through the use of point-of-sale shelf signs that contain the following language:

> **WARNING:** This product contains a chemical known to the state of California to cause birth defects or other reproductive harm.

The Federal Hazardous Substances Act preempts "cautionary labeling requirements" imposed by states. "Label" includes accompanying literature, but only if that accompanying literature contains directions for use.

This case raises a narrow question -- whether a point-of-sale shelf sign containing the language, "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm," is a direction for use and therefore a form of "labeling" preempted by the FHSA.

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OPINION BELOW

The California Court of Appeal's opinion is reported at 53 Cal.App.4th 1373, 62 Cal. Rptr.2d 368. The California Supreme Court's order denying review is unreported.

JURISDICTION

The California Court of Appeal entered judgment on March 31, 1997. The California Supreme Court denied review on July 9, 1997. Petitioners have invoked the jurisdiction of this Court under 28 U.S.C. section 1257(a).

STATUTORY AND REGULATORY PROVISIONS

The relevant provisions of the Federal Hazardous Substances Act, 15 U.S.C. sections 1261-1277, and its implementing regulations, 16 CFR sections 1500.1 et seq., and the relevant provisions of Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, California Health & Safety Code sections 25249.5 et seq., and its implementing regulations, 22 California Code of Regulations sections 12000 et seq., are set forth in the Appendix.

STATEMENT OF THE CASE

For the second time, this Court has been asked to decide whether Proposition 65 point-of-sale signs are directions for use and are therefore labels preempted by the Federal Hazardous Substances Act. The Court first faced this question in 1992 when it denied certiorari to review the Ninth Circuit decision in *Chemical Specialty Manufacturers Association, v. Allenby*, 958 F.2d 941 (CA9), *cert. denied, Chemical Specialty Manufacturers Association v. Book*, 506 U.S. 825 (1992). The identical issue has now found its way through the state system, with the same result: The state trial and appellate courts have concluded that a Proposition 65 point-of-sale sign is not a label preempted by the FHSA. Because the question involves a statute that is unique to California, the narrow issue presented has been put to rest and will not likely arise again, in either state or federal court, unless this Court decides to take review.

A. Statutory Framework

1. Proposition 65

Proposition 65 is a "right to know" initiative passed by a vote of the People of the State of California in November, 1986. The portion of the statute at issue here is the warning requirement contained in California Health and Safety Code ("Cal. Health & Saf. Code") section 25249.6:

> No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . .

The statute provides that the warning may be given by general methods such as "labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable." *Id.*, § 25249.11(f). Warnings are not required where the party causing the exposure can show that the exposure causes no significant risk or will have no observable effect. *Id.* § 25249.10.

Implementing regulations promulgated by the State further identify certain methods of providing warnings for consumer products that are deemed to comply with the statute (i.e., "safe harbors"), but also allow businesses to use other warning methods that are "clear and reasonable." 22 California Code of Regulations ("Cal. Code Regs.") § 12601(b). For consumer products,the "safe harbors" include (1) product labeling and (2) "shelf labeling, signs, menus or a combination thereof" containing specified language. *Id.*[1/]

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1. All types of shelf labeling signs or any other material

For reproductive toxins the safe harbor language is "**WARNING**: This product contains a chemical known to the state of California to cause birth defects or other reproductive harm." 22 Cal. Code Regs. § 12601(b)(4)(B).

Toluene, the chemical at issue in this case, was listed as a reproductive toxin on January 1, 1991. 22 Cal. Code Regs. § 12000. Exposures to toluene were therefore subject to the warning requirement as of January 1, 1992. Cal. Health & Saf. Code § 25249.10(b).

2. The Federal Hazardous Substances Act

The Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261 et seq., requires that certain consumer products that are "hazardous substances" must provide cautionary labels on their products. 15 U.S.C. § 1261(p). In 1966, Congress adopted what it described as a "limited" preemption amendment intended to protect manufacturers from the need to label each product specially to comply with different state and local requirements. H.R. Rep. No. 2166, 89th Cong., 2d Sess. 6, *reprinted in* 1966 U.S. Code Cong. & Admin. News, p. 4095, 4097, 4100.

In 1976, Congress narrowed this provision, limiting preemption to instances where there is a federal cautionary labeling requirement in effect designed to protect against a risk of illness or injury, and a state imposes a different cautionary labeling requirement for the same risks:

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displayed with the product in the store, as distinguished from package labeling, will be referred to herein as "point-of-sale" signs.

> . . . if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(b) or 3(b) [15 U.S.C. sections 1261(p) or 1262(b)] designed to protect against a risk of illness or injury associated with the substance, no State . . . may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under 2(p) or 3(b).

15 U.S.C. § 1261 note.

In adopting this preemption provision, Congress specifically rejected the idea of imposing uniform national labeling requirements. *See* S.R. No. 94-251, 94th Cong., 2d Sess., *reprinted in* 1976 U.S. Code Cong. & Admin. News 1004.

The FHSA does not define the term "cautionary labeling requirement." It does, however, define "label" as "a display of written, printed or graphic matter upon the immediate container of any substance. . ." It is beyond dispute that a point-of-sale sign is not a label in the narrow sense of that definition under the FHSA, but the definition also provides that a requirement that information appear on the label is not complied with unless the information also appears "on all accompanying literature where there are directions for use, written or otherwise." 15 U.S.C. section 1261(n). By regulation, the CPSC similarly defined "accompanying literature" to include any written material "that provides direction for use." 16 CFR § 1500.3(c)(9).[2/]

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2. *See also* 16 CFR section 1500.121(c)(6) ("Where literature accompanying the package of a hazardous

Thus, the FHSA's labeling requirements extend to accompanying literature only when that literature provides directions for use.

When the preemption provision of the FHSA is viewed in conjunction with the statutory and regulatory definitions of "label" and "accompanying literature," it is clear that the FHSA preempts state warnings only when they are imposed on the label itself or on accompanying literature containing directions for use.

B. The Prior Litigation

The arguments advanced by TruServ Corporation, formerly Cotter & Company ("Cotter") are not new.[3/] In 1989, the Chemical Specialties Manufacturers Association ("CSMA") sued the State of California in federal court, alleging that Proposition 65 was preempted by the FHSA. The federal district court determined that Proposition 65 point-of-sale signs do not contain directions for use, are not labeling under the FHSA, and therefore are not preempted. *Chemical Specialties Manufacturers Association ("CSMA") v. Allenby*, 744 F.Supp. 934 (N.D. Cal. 1990). The Ninth Circuit Court of Appeals unanimously affirmed in *CSMA v. Allenby*, 958 F.2d 941 (1992). CSMA filed a petition for

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substance has directions for use, written or otherwise, section 2(n) of the Act requires the literature to bear cautionary labeling"; 16 CFR section 1500.125 ("When any accompanying literature includes or bears any directions for use (by printed word, picture, design or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act. . .")

3. For ease of reference, the People will continue to refer to both Cotter & TruServ Corporation as "Cotter."

writ of certiorari, raising the same argument that is presented here. Petition for Writ of Certiorari No. 91-1957 at 25-28. This Court denied the petition on October 5, 1992. *CSMA v. Book*, 506 U.S. 825 (1992).

In 1993, the People sued Cotter under Proposition 65, alleging that Cotter failed to warn of exposure to toluene, a reproductive toxin, from its spray paints. Cotter argued that Proposition 65 was preempted by the FHSA. The trial court, relying on the Ninth Circuit's *Allenby* decision, ruled that Proposition 65 could be complied with through point-of-sale signs, that the safe harbor warning language was not a direction for use, and therefore the point of sale signs were not labeling as defined by the FHSA and were not preempted. Cotter appealed and the Court of Appeal unanimously affirmed the decision of the trial court. *People v. Cotter & Company*, 53 Cal.App.4th 1373. The California Supreme Court denied review on July 9, 1997. 1997 Cal. LEXIS 4215 (1997).

C. The Court of Appeal Decision

The California Court of Appeal began with the well-accepted presumption that the traditional police powers of the state are not to be displaced by federal law unless that is the clear and manifest intent of Congress. *Cotter*, 53 Cal.App.4th at 1380. With this presumption as a backdrop, the Court of Appeal came to the same simple and inescapable conclusions reached by both federal courts and the state trial court -- that the FHSA preempts only labeling requirements; that accompanying literature is considered part of the product labeling only when that literature contains directions for use; and that Proposition 65 point-of-sale warning signs do not contain directions for use, are not labeling under the FHSA and therefore are not preempted. *Id.* at 1386-1393. The Court reasoned that if Congress had wanted to preempt all accompanying literature and all

warnings, as Cotter argued, it could have so specified. *Id.* at 1387.[4]

REASONS FOR DENYING THE PETITION

Cotter urges this Court to grant certiorari to resolve perceived conflicts concerning preemption of common law claims under the FHSA, the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA") and the Medical Device Amendments to the Food, Drug and Cosmetics Act. Far from being an ideal vehicle to resolve the alleged conflicts, this case presents a narrow and limited question of statutory definition that has little implication to the issues raised by Cotter.

The FHSA, which regulates household toxins, preempts only state imposed "cautionary labeling requirements." The critical question therefore is whether a Proposition 65 point-of-sale sign is a state imposed cautionary labeling requirement.

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4. The *Cotter* Court also addressed a second, highly fact-specific, issue -- whether Cotter had shown that it was impossible for it to comply with Proposition 65 through the use of point-of-sale signs. The Court concluded that the trial court did not err in concluding that Cotter had failed to meet its burden of proof in this regard and therefore Proposition 65 did not present a de facto labeling requirement that was preempted by federal law. *Cotter*, 53 Cal.App.4th at 1396. This issue has not been raised in this Petition. Thus, it is undisputed that Cotter can comply with Proposition 65 without making any changes to the label on its products.

Ignoring the express language of the statute, Cotter argues that any warning requirement, whether it is a labeling requirement or not, is preempted, simply because any additional warning implicitly challenges the adequacy of the label. Cotter suggests therefore that not only are label warnings preempted, but so too are letters, phone calls to customers or newspaper ads. Petition for Writ of Certiorari ("Petition") at 26. In effect, Cotter argues that Congress has implicitly occupied the entire field of warnings in whatever channel of communication.

Cotter's argument is directly contrary to the express language of the statute, which preempts only **labeling** requirements. While Congress certainly could have occupied the field and preempted all warnings in whatever channel of communication, it simply did not do so.

Furthermore, there is no conflict between the result reached by the Court of Appeal and the decisions of numerous courts concerning preemption of common law failure to warn claims under both the FHSA and FIFRA. Quite to the contrary, while the courts have consistently found preemption of common law failure to warn claims that directly challenge the adequacy of the label, they have declined to find preemption of state statutory warning requirements that are imposed outside of and without regard to the label.

Finally, the Court of Appeal's application of *Medtronic, Inc. v. Lohr*, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) is correct, but even if it were not, this case does not merit review. The result reached by the Court of Appeal would be the same, even independent of the *Medtronic* analysis. There simply is no basis under the FHSA to hold, as Cotter urges, that Congress implicitly occupied the whole field of warnings, even while explicitly preempting only "labeling requirements."

I.

THE *COTTER* DECISION INVOLVES A UNIQUE STATE LAW AND A NARROW QUESTION OF STATUTORY INTERPRETATION, WHICH DOES NOT PRESENT NATIONWIDE ISSUES MERITING THIS COURT'S REVIEW

This case raises a peculiarly narrow question -- whether a point of sale sign containing the language "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm" is a direction for use and therefore a form of "labeling" preempted by the FHSA. The question will not likely arise again, because Proposition 65 is a California statute, and the issue has been resolved both by the Ninth Circuit and by the lower state courts.

Ignoring the specifics of the case, Cotter focuses only on the broadest of generalities, arguing that the Court should grant review because the FHSA applies to hundreds of thousands of products; because many other statutes preempt labeling; and because it alleges there is widespread confusion with this Court's decision in *Medtronic*. Petition at 21-23.

The focus on generalities blurs the narrow scope of the *Cotter* decision, a decision that deals with a single state statute and a narrow definitional question under the FHSA.

II.

THE *COTTER* DECISION IS CORRECT

A. The Statute is Clear: Only Labeling Requirements are Preempted

Cotter's argument is simple. It asserts that any state imposed cautionary requirement, in any channel of communication, whether labeling or not, is preempted because additional cautionary statements implicitly challenge the adequacy of the label warning. In effect, Cotter asks the Court to ignore the clear language of the FHSA which preempts only "cautionary labeling requirements," 15 U.S.C. § 1261 note, and to find implied occupation of and preemption of the entire field of warnings.

This argument is wrong. As stated by this Court in *Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 517 (1992), "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted." In *Cipollone*, where the act in question preempted only state laws with respect to "advertising or promotion" of cigarettes, state law duties to disclose facts through "channels of communication other than advertising or promotion" were not preempted." *Id.* at 528.

Here too, where the FHSA preempts only cautionary labeling requirements, state law duties to warn in channels of communication other than labeling are not preempted.

Furthermore, congressional concern with minimizing the burdens on manufacturers from having to prepare multiple product labels,[5] is not associated with point-of-sale warnings, which can be prepared and distributed separately to meet the requirements of individual states. Thus, there is nothing in the legislative history of the FHSA that indicates that Congress intended to prohibit a state from communicating information to its citizens in channels other than labeling in order to enable them to make informed purchasing decisions. *Cf. American Meat Institute v. Ball*, 424 F.Supp. 758, 766 (W.D. Mich. 1976) (reaching same conclusion concerning the Federal Wholesome Meat Act).

Finally, while the result is not what Cotter may have wanted, it is the only result that is consistent with the plain language of the statute. Congress did not accidentally choose the "cautionary labeling requirements" language for the preemption provision to the statute. It used the language deliberately and it is this language which circumscribes the scope of the limited preemption granted by Congress. Thus, Cotter's quarrel is with Congress, not with the interpretations of the courts and it should not be permitted to circumvent the intent of Congress and seek from the courts what it could not obtain from Congress.

B. The FHSA Preempts Accompanying Literature Only When it Contains Directions for Use

Cotter next argues that, even if the statute means what it says, and preempts only "labeling" requirements

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5. H.R. Rep. No. 2166, 89th Cong., 2d Sess. 6, *reprinted in* 1966 U.S. Code Cong. & Admin. News, pp. 4095, 4097, 4100.

rather than all warnings, the Court of Appeal should have defined labeling to include all accompanying literature, not just accompanying literature that contains directions for use. Understandably dissatisfied with the narrow language used by Congress in the FHSA, the only statute at issue in this case, Cotter attempts to turn this Court's attention to language used in other statutes such as the Food Drug and Cosmetics Act and FIFRA, that define labeling to include all accompanying literature, not just accompanying literature that contains directions for use. Petition at 28.

There is no need to look beyond the FHSA and its implementing regulations, however. While the FHSA does not define "labeling" specifically, it shows an awareness of the distinction between package labeling and accompanying literature and makes clear that the FHSA regulates accompanying literature as labels only when that literature contains directions for use. *See* 15 U.S.C. § 1261 note.

Furthermore, rather than treating the term "labeling" as distinct from "label," as Cotter suggests, the FHSA and its implementing regulations use the terms label and labeling interchangeably. For example, the preemption provision at issue here, section 1261 Note, refers to "cautionary **labeling** requirements under section 2(p) or 3(b) [15 U.S.C. §§ 1261(p), 1262(b)]." Section 1261(p) refers both to the "packaging or **labeling** of" a substance and to a substance that "fails to bear such **label**." Section 1262(b) refers to "additional **label** requirements" and a substance that "fails to bear a **label**." (emphasis added in all) The regulations similarly use the terms interchangeably.[6/]

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6. *See* 16 C.F.R. § 1500.14(b) (Commission finds that for certain substances "**labeling** required by section 2(p) of the act is not adequate. . . the following specific **label** statements are deemed necessary to supplement the **labeling**

In the end, Cotter's argument is futile. Even if the Court were to accept Cotter's argument that labeling should be defined to include all accompanying literature, the term "accompanying literature" is itself defined narrowly in the regulations to include only literature that provides directions for use. 15 C.F.R. section 1500.3(c)(9) ("'accompanying literature' is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device **that provides directions for use**, written or otherwise. . . .") (emphasis added). Thus, even if all accompanying literature is preempted, a Proposition 65 point-of-sale sign is not considered accompanying literature, according to the regulatory definition, because it does not contain directions for use, and therefore is not preempted.

C. A Proposition 65 Warning is Not a Direction for Use

Finally, driven yet one more step back into the express language of the statute, Cotter argues that, even if the FHSA preempts only warnings in accompanying literature containing directions for use, a Proposition 65 point-of-sale sign is an implied direction for use and therefore is preempted. Cotter relies on a March, 1991 advisory opinion from the general counsel of the Consumer Product Safety Commission ("CPSC") stating that the Proposition 65 safe harbor warning should be considered a

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required by section 2(p)(1) of the act. . . ." (emphasis added); 16 C.F.R. section 1500.15 "**Labeling** of fire extinguishers"; substance, when used according to "**label** directions" shall bear the following "**labeling**"; 15 C.F.R. § 1500.82(a) ("Exemption from full **labeling** and other requirements"; "Any person who believes a particular hazardous substance. . . should be exempted from full **label** compliance. . . ." (emphasis added in all).

label under the FHSA, because the warning, while not an express direction for use, implies that "steps should be taken to minimize or eliminate exposure." Advisory Opinion No. 312 at 4.[7]

The Court of Appeal, like the Ninth Circuit, the federal district court and the state trial court before it, did not simply decide that another reading of the FHSA was "more reasonable" than the CPSC general counsel's reading. It decided that the general counsel's interpretation was contrary to the language of the statute as well as to the strong presumption against preemption of state health and safety statutes and was therefore entitled to no deference. *Cotter*, 53 Cal.App.4th at 1393. *See Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.* 467 U.S. 837, 842 (1984) (agency interpretation that is "arbitrary, capricious, or manifestly contrary to the statute. . . ." is not entitled to deference). This conclusion, reached by eight different judges, is correct. By conflating warnings and directions for use, the CPSC opinion ignores the clear language of the statute, which distinguishes between warnings and directions for use, and impermissibly broadens the scope of preemption to include warnings on all accompanying literature whether the accompanying literature contains directions for use or not.

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7. The CPSC letter was previously presented to this Court in June of 1992 in the CSMA's Petition for Writ of Certiorari (No. 91-1957). CSMA made the same argument as Cotter makes here, i.e., that the court, (in that case the Ninth Circuit) wrongly declined to follow the CPSC interpretation. CSMA Petition at 27-29.

D. The Principles that the Court of Appeal Derived from *Medtronic* are Accurate and the Result would be the Same, even Independent of the Medtronic Analysis

Cotter also argues that review is warranted because the Court of Appeal wrongly applied *Medtronic's* general/specific distinction outside of the context of the Medical Device Amendments. Petition at 29-30. The Court of Appeal's application of *Medtronic* to this case was both limited and correct. The Court of Appeal first looked to the exact words of the FHSA, noting that "Congress chose to restrict the definition of a label to include accompanying literature only when that material contains 'directions for use.' (15 U.S.C. § 1261(n).)" *Cotter*, 53 Cal.App.4th at 1387. It went on to note that "if Congress wanted preemption under the FHSA to apply to all accompanying literature with 'implied' directions for use, as Cotter argues, Congress could have specified that." *Id.* The Court of Appeal further stated that it would interpret the words in the preemption provision narrowly and concluded that, based on the generality of the FHSA, point of sale signs "are unlikely to interfere with the federal government's objectives." 53 Cal.App.4th at 1388.

This analysis is consistent with the entire realm of supremacy clause jurisprudence, in particular with the two fundamental principles of preemption analysis, first that the presumption against preemption of state police powers mandates a narrow interpretation of preemption provisions, *Medtronic*, 116 S.Ct. at 2250, *Cipollone*, 505 U.S. at 518, and second, that preemption analysis requires a careful comparison to determine whether "a particular state requirement threatens to interfere with a specific federal interest." *Medtronic*, 116 S.Ct. at 2257; *Cipollone*, 505 U.S. at 524-530 (performing detailed comparison between

each of the state requirements and the federal interest at issue as expressed in the preemption provision of the statute).

Finally, the fact that the *Cotter* court drew general lessons from *Medtronic*, while other courts have declined to do so, does not present a conflict that merits review in this case. Even if the Court of Appeal were incorrect in its application of the *Medtronic* reasoning, its ultimate conclusions -- that Proposition 65 point of sale signs are not cautionary labeling requirements and are not preempted by the FHSA -- are inescapable and are consistent with *Cipollone* and all of the relevant case law.

III.

THE COTTER DECISION DOES NOT CONFLICT WITH THE DECISIONS OF OTHER COURTS

Focusing on generalities and ignoring the specific and narrow ruling of this case, Cotter argues that the Court of Appeal's decision conflicts with decisions of other courts. These "conflicts" are illusory.

A. The *Cotter* Decision Does Not Conflict with Decisions Holding that the FHSA Preempts Common Law Failure to Warn Claims that Directly Challenge the Adequacy of the Label

Far from being "deeply divided," as Cotter suggests, the case law concerning preemption of common law warning claims is consistent. Of the FHSA cases cited by Cotter, all were based on common law failure to warn claims that directly challenged the adequacy of the label and,

with one somewhat ambiguous exception, all concluded that such claims were preempted by the FHSA.[8/]

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8. *See, Comeaux v. National Tea Co.*, 81 F.3d 42, 43 (CA5 1996) (per curiam) (only issue raised on appeal was adequacy of warnings provided by product); *Moss v. Parks*, 985 F.2d 736, 740 (CA4) *cert. denied*, 509 U.S. 906 (1993) ("In actions such as the present one, if the plaintiff requests a label that is 'more elaborate or different' than the one required by the FHSA and its regulations, the claim is preempted.") *Lee v. Boyle*, 792 F.Supp. 1001, 1007-08 (W.D. Pa. 1992) (common law claims preempted because they mandate different labeling requirements than the FHSA); *Salazar v. Whink*, 881 P.2d 431, 432-33 (Colo.Ct.App.), *cert. denied*, 1994 Colo. LEXIS 793 (1994) (issue concerned adequacy of warning on product; state common law duty to warn is nothing more than a duty to label a product to provide information); *Busch v. Graphic Color Corp.*, 169 Ill.2d 325, 662 N.E.2d 397, 401, 405-06 (Ill.), *cert. denied*, 136 L.Ed.2d 18, 117 S.Ct. 55 (1996) (claim preempted because plaintiff argued that label warning was insufficient and that additional warnings needed to be included on the label) *State ex rel Jones Chemicals Inc. v. Seier*, 871 S.W.2d 611, 614 (Mo.App. E.D. 1994) (FHSA preempts state common law failure to warn claims based on the adequacy of the label to the extent that those claims would create labeling requirements different from under the FHSA); *Canty v. Ever-Last Supply Co.*, 296 N.J. Super. 68, 685 A.2d 1365, 1374 (N.J. Super.L 1996) ("Where a plaintiff's claim seeks to hold a manufacturer responsible for failing to provide warning labels which are not identical to those required under the FHSA, that claim is preempted."); *Beyrle v. Finneron*, 229 A.D.2d 1010, 645 N.Y.S.2d 192, 193 (A.D. 4 Dept. 1996) (claim alleging that product label did not contain adequate warnings); *Wallace v. Parks Corp.*, 212 A.D.2d 132, 629 N.Y.S.2d 570, 573-74 (A.D. 4 Dept.

Regardless of whether these courts correctly found preemption of state tort laws, none of the cases addressed the specific question here, i.e., whether the FHSA preempts state statutory non-label warning requirements. While this Court may someday need to face the question of whether the preemptive language of the FHSA was intended to preempt state common law tort claims, it would be ill-advised to do so in a case that involves neither tort law nor a product label.

B. The Cotter Decision Does Not Conflict with Decisions Holding that FIFRA Preempts Common Law Failure to Warn Claims

Cotter next suggests that the Court should review this case so that it can resolve perceived conflicts regarding preemption under FIFRA, an entirely different statute. Again, this case is a poor vehicle, at best, for such an excursion.

1995) (allegations that warnings on container were inadequate; prevailing rule is that plaintiff's claims are preempted only to the extent they require a showing that label and package should have included additional or different warnings); *Jenkins v. James B. Day & Co.*, 69 Ohio St.3d 541, 634 N.E.2d 998, 1004-05 (Ohio 1994) (no preemption of common law claim for failure to provide warning where the plaintiff alleges that label failed to comply with FHSA).

The only case cited to the contrary, *Duplin v. Whink Products, Co*, 1994 WL 197612 (Conn.Super.Ct., May 2, 1994) is ambiguous in its holding and appears to rule only that a claim of failure to comply with the warning requirements of the FHSA is not preempted.

Furthermore, despite Cotter's efforts to show conflicts, the case law under FIFRA is surprisingly consistent. A long line of cases, including cases from the First, Fourth, Fifth, Seventh, Eighth, Ninth, Tenth, and Eleventh Circuits[9], holds that common law failure to warn claims are preempted by FIFRA.[10] Several of these cases conclude that a common law failure to warn claim is preempted even if the plaintiff alleges that a warning should have been given outside the label.[11] Presumably these

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9. *See, e.g., King v. E.I. Dupont De Nemours & Co.*, 996 F.2d 1346, 1349-50 (CA1) *cert. dismissed*, 510 U.S. 985 (1993); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 748 (CA4 1993); *MacDonald v. Monsanto Co.*, 27 F.3d 1021, 1024-25 (CA5 1994); *Shaw v. Dow Brands, Inc.*. 994 F.2d 364, 369-71 & n.4 (CA7 1993); *Bice v. Leslie's Poolmart, Inc.*, 39 F.3d 887, 888 (CA8 1994); *Taylor AG Indus. v. Pure-Gro*, 54 F.3d 555, 561 (CA9 1995); *Arkansas-Platte & Gulf Parntership v. Van Waters & Rogers, Inc.*, 981 F.2d 1177, 1179 (CA10), *cert. denied*, 510 U.S. 813 (1993); *Papas v. Upjohn*, 985 F.2d 516, 518-19 (CA11) *cert. denied*, 510 U.S. 913 (1993).

10. The only case to the contrary, *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542 (CA D.C.), *cert. denied*, 469 U.S. 1062 (1984) was based on a ruling that common law damage claims do not impose any requirements on the manufacturer and therefore are not preempted. That decision may no longer be good law in light of this Court's decision in *Cipollone*, but regardless, its holding has nothing to do with this case.

11. *See Papas v. Upjohn*, 985 F.2d at 519; *Worm v. American Cyanamid Co.*, 5 F.3d at 748; *Taylor AG Indus. v. Pure-Gro*, 54 F.3d at 561; *Goodwin v. Bacon*, 127 Wash.2d 50, 896 P.2d 673, 681 (Wash. 1995); *Jenkins v. Amchem Prods., Inc.*. 256 Kan. 602, 886 P.2d 869, 881-81

cases rely on the generally accepted recognition that the common law duty to warn "is nothing more than a duty to label a product to provide information." *Arkansas-Platte & Gulf v. Van Waters & Rogers* 981 F.2d 1177, 1179, (CA10) *cert. denied* (1993) 519 U.S. 813. *See also King v. E.I. Du Pont De Nemours & Co.*, 806 F.Supp. 1030, 1037, n.4 (D.Me. 1992), *aff'd* 996 F.2d 1346 (CA1 1993) ("We can see no more effective way to warn potential users of the dangers of a product than by product labels.")

A separate and distinct line of cases under FIFRA and similar federal laws concerns state statutes that impose non-label warning requirements without regard to the contents of the product label. Again, the decisions are uniform, all declining to find preemption. Thus, in *New York State Pesticide Coalition, Inc. v. Jorling*, 874 F.2d 115, 116-17 (CA2 1989), the court held that state requirements concerning warnings to the general public on signs, posted notices and newspaper advertisements did not constitute labeling under FIFRA and were not preempted. As noted by the court, FIFRA was intended to set standards for pesticide labeling, "not to prevent states from regulating the 'sale and use' of the poisonous chemical substances through mandatory written, printed or graphic materials revealing the ingredients." (*Id.* at 119.)

The *Jorling* decision is consistent with cases interpreting analogous preemption provisions in other federal laws as well. These cases similarly have held that preemption of "labeling" requirements does not apply to statutes that regulate information provided in non-label channels of communication such as posted notices, advertising, menus, etc. *See National Broiler Council v. Voss*, 44 F.3d 740, 748-49 (9th Cir. 1994) (portion of state

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(Kan. 1994) *cert. denied*, 116 S.Ct. 80 (1995).

law prohibiting advertising of poultry products as fresh, not preempted by federal Poultry Products Inspection Act, 21 U.S.C. § 467e, which precludes state labeling requirements); *Grocery Mfrs. of America v. Gerace*, 755 F.2d 993, 996, 1002-03, 1006 (CA2 1985) *cert. denied* 474 U.S. 820 (1985) (New York law regarding information on signs, menus and serving containers was not preempted by federal Food, Drugs and Cosmetics Act, Meat Inspection Act and Poultry Products Inspection Act, even though package labeling requirements were preempted); *American Meat Institute v. Ball*, 424 F.Supp. 758, 763, 766 (W.D. Mich. 1976) (notices required by state law to be posted in restaurants are not labels and not preempted by federal Wholesome Meat Act, 21 U.S.C. § 678, prohibiting state "labeling requirements").

Thus, the case law divides along obvious and distinct lines. Where common law failure to warn claims are at issue, the FIFRA cases are nearly uniform in holding that such claims are preempted. In contrast, where a state statute requires information to be communicated in non-label channels, the case law is equally consistent in hold that the state requirement is not preempted. The Ninth Circuit's decision in *Allenby* falls comfortably into the latter line of cases as does the decision of the Court of Appeal in *Cotter*.

C. The Court of Appeal's Reasoning that FIFRA and FHSA Preemption are not Absolutely Identical is Correct and is Consistent with the Decisions of This and Other Courts

The substantive decision of the Court of Appeal is both correct and consistent with the case law under the FHSA, FIFRA and related statutes. The Court of Appeal's reasoning is equally unassailable. It recognized, as have

many courts,[12] that the preemption provisions in FIFRA and the FHSA are "essentially identical." *Cotter*, 53 Cal.App.4th at 1390, n.16. The *Cotter* Court, however, noted significant differences as well: First, that FIFRA defines "labeling" to include all written material accompanying the pesticide at any time, 7 U.S.C. § 136(p)(2), whereas the FHSA limits the definition to accompanying literature that contains directions for use, 15 U.S.C. § 1261(n); and second, that the EPA approves the actual label under FIFRA, whereas, under the FHSA, the Consumer Product Safety Commission does not.[13] These differences have been noted by other courts as well. *See Jenkins v. James B. Day & Co.*, 634 N.E.2d at 1004 n.4

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12. *See Busch v. Graphic Color Corp.*, 662 N.E.2d at 405 (FIFRA provision is "substantively equivalent" to the FHSA's preemption provision.); *Moss*, 985 F.2d at 740 n.3 ("The preemption language of the two statutes is nearly identical."); *Comeaux*, 81 F.3d at 43-44 (referring to "almost identical preemptive provisions" of FIFRA and FHSA).

13. EPA's extensive oversight of pesticide labels under FIFRA has frequently been cited as a basis for preemption. *See, e.g., Papas*, 985 F.2d at 519 ("If a pesticide manufacturer places EPA-approved warnings on the label and packaging of its product, its duty to warn is satisfied and the adequate warning issue ends."); *Worm*, 5 F.3d at 747 ("Given the comprehensive nature of the FIFRA labeling process, it is apparent that [FIFRA's preemption provision] dictates preemption of any state common law cause of action that rests on an alleged failure to warn or communicate information about a product through its labeling."); *Taylor AG*, 54 F.3d at 560 (discussing rigorous label approval process under FIFRA); *King*, 806 F.Supp. at 1036 (because labels were approved by the EPA under FIFRA, failure to warn claim is preempted).)

("Our analysis could be different if we were considering whether a plaintiff's inadequate labeling claim is preempted by FIFRA, rather than by the FHSA").

The Court of Appeal's refusal to blindly apply FIFRA preemption analysis to the FHSA is absolutely consistent with this Court's numerous rulings that congressional intent is the touchstone of preemption analysis and is to be discerned from the language of the statute, the statutory framework and the structure and purpose of the statute as a whole. *See Medtronic*, 116 S.Ct. at 2250-51 (citing *Cipollone*, 505 U.S. at 516; 112 S.Ct. at 2617; *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 96, 111, 112, 112 S.Ct. at 2381-2382, 2383, 2390; *Malone v. White Motor Corp.*, 435 U.S. 479, 504, 98 S.Ct. 1185, 1190, 55 L.Ed.2d 443 (1978).) FIFRA and the FHSA are different statutes, enacted by different congresses in different time periods, with different regulatory schemes. It would be improper for any court simply to superimpose a preemption analysis under one statute on the other.

Finally, the Court of Appeal's analysis that FIFRA and FHSA preemption are not absolutely identical is not dispositive of this case. Even under FIFRA, the courts have concluded that Proposition 65 point-of-sale signs are not preempted. *Allenby*, 958 F.2d at 947. Thus, the "conflict presented by Cotter has no bearing on the outcome of the case and does not merit review by this Court.

D. The Court of Appeal's Distinction Between Common Law Failure to Warn Claims and Proposition 65 is Correct and Does Not Conflict with This Court's Decisions

Cotter argues that the Court of Appeal's distinction between preemption of common law failure to warn claims and state statutory non-label warning requirements conflicts with the decisions of this Court holding that the term "requirements," for purposes of preemption analysis, applies equally to requirements imposed through common law and through state statutes. Petition at 15. The meaning of the term "requirements," however, was never presented in this case. All parties have always acknowledged that Proposition 65 is a "requirement" for purposes of preemption analysis. The only issue is whether it is a "**labeling**" requirement. Thus, the rulings by this Court that common law claims and statutory enactments are encompassed in the term "requirements" do not apply.

Finally, Cotter argues that the Court of Appeal mistakenly applied the standards for facial preemption to an as-applied challenge to Proposition 65. Petition at 15. In fact, however, as presented by Cotter and framed by the Court of Appeal, the issue presented was a classic facial challenge to the statute: "Does the FHSA preempt Proposition 65 warnings because point of sale signs are labels as defined by the FHSA?" *Cotter*, 53 Cal.App.4th at 1379.[14/] The standard applied by the Court of Appeal was therefore correct and does not conflict with the decisions of this or any other court.

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14. As noted previously, note 3 *supra*, Cotter did raise an as-applied challenge to Proposition 65. That issue is not, however, before this Court.

CONCLUSION

For the second time, this Court has been presented with the same narrow question of the definition of cautionary labeling requirements under the FHSA, and its application to Proposition 65. The ruling of the California Court of Appeal is correct and consistent with all of the relevant case law, as were the earlier rulings of the federal courts. The petition for writ of certiorari should be denied.

Respectfully submitted,

DANIEL E. LUNGREN
Attorney General
RODERICK E. WALSTON
Chief Assistant Attorney General
THEODORA BERGER
Assistant Attorney General
CRAIG C. THOMPSON
EDWARD G. WEIL
SUSAN S. FIERING*
Deputy Attorneys General
(*Counsel of Record)

Attorneys for Respondent the
People of the State of California

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or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).)

DISCUSSION

Cotter raises two issues on appeal: (1) Does the FHSA preempt Proposition 65 warnings because point of sale signs are labels as defined by the FHSA? (2) If point of sale signs are not labels, does the FHSA still preempt Proposition 65 because the state statute imposes a de facto labeling requirement? We address each of these issues separately.

I. *Point of Sale Signs Are Not Labels Under the FHSA*

(1a) Cotter contends the court erred in denying its summary judgment motion because Proposition 65 imposes a "cautionary labeling requirement" which is preempted by the FHSA. Since Cotter presents a facial challenge to Proposition 65, it must establish Proposition 65 would not be valid under any set of circumstances. (*Chemical Specialties Mfrs. Ass'n, Inc.* v. *Allenby* (9th Cir. 1992) 958 F.2d 941, 943, cert. den. (1992) 506 U.S. 825 [113 S.Ct. 80, 121 L.Ed.2d 44] (*Allenby*).) Thus, to find preemption, we " 'must determine that *all* possible consumer product warnings that would satisfy Proposition 65 conflict with provisions' " of the FHSA. (*Comm. of Dental Amalgam Mfrs. & Distribs.* v. *Stratton* (9th Cir. 1996) 92 F.3d 807, 810 (*Stratton*).)

The People claim Cotter could satisfy Proposition 65 by using point of sale signs. This method, they assert, does not conflict with the preemption provision of the FHSA. They rely on *Allenby*, *supra*, 958 F.2d 941, which held such signs are not labels under the FHSA. Cotter, however, claims the Ninth Circuit in *Allenby* misapplied and misinterpreted federal and state law and the trial court erred by following *Allenby*.

In deciding whether *Allenby* represents good law, we first review the federal preemption doctrine and examine the most recent United States

Supreme Court decisions. We then explain why *Allenby* correctly found point of sale signs are not labels under the FHSA.

A. *Standard of Review*

The trial court denied Cotter's motion for summary judgment based on preemption and granted the People's motion for summary adjudication to Cotter's defense of preemption. Summary adjudication was proper only if the defense of preemption presented no triable issue of material fact and Cotter could not raise the defense as a matter of law. (Code Civ. Proc., § 437c, subd. (f)(1).) Since the parties do not dispute the facts related to preemption and the summary adjudication raises a purely legal question, we employ de novo review. (*Schrader* v. *Scott* (1992) 8 Cal.App.4th 1679, 1684 [11 Cal.Rptr.2d 433].)

B. *Preemption Doctrine*

(2) "Preemption analysis starts with the presumption that the traditional police powers of states are not displaced by federal law unless displacement was the 'clear and manifest purpose of Congress.' " (*Allenby, supra*, 958 F.2d 941, 943; accord with *Medtronic, Inc.* v. *Lohr* (1996) __ U.S. __, __ [116 S.Ct. 2240, 2248, 135 L.Ed.2d 700] (*Medtronic*).)[6] One reason for this presumption is Congress has the power to make its intention clear. "[I]f the court erroneously finds preemption, the State can do nothing about it, while if the court errs in the other direction, Congress can correct the problem." (958 F.2d at p. 943.)

The second presumption underlying a preemption analysis requires a determination of Congress's purpose, which " 'is the ultimate touchstone' in every pre-emption case. [Citations.]" (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2250].) We determine intent primarily "from the language of the pre-emption statute and the 'statutory framework' surrounding it. [Citation.]" (*Id.* at p. __ [116 S.Ct. at p. 2251].) "Also relevant, however, is the 'structure and purpose of the statute as a whole,' [citation], as revealed not only in the text, but through the reviewing court's reasoned understanding of

[6]Justice Stevens delivered the opinion of the court. Justices Kennedy, Souter, Ginsburg, and Breyer joined with respect to __ U.S. at pages __-__ [116 S.Ct. at pages 2245-2251] (pts. I, II, and III); __ U.S. at pages __-__ [116 S.Ct. at pages 2253-2258] (pt. V); and __ U.S. at page __ [116 S.Ct. at page 2259] (pt. VII). Justices Kennedy, Souter, and Ginsburg joined with respect to __ U.S. at pages __-__ [116 S.Ct. at pages 2251-2253] (pt. IV) and __ U.S. at pages __-__ [116 S.Ct. at pages 2258-2259] (pt. VI). Justice Breyer filed an opinion concurring in part and concurring in the judgment. Justice O'Connor filed an opinion concurring in part and dissenting in part, in which Justices Rehnquist, Scalia, and Thomas joined. All references, unless otherwise specified, refer to Justice Stevens's opinion.

he way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." (*Ibid.*)

(3) If the statute does not have an express preemption clause, state law is only preempted if (1) the law actually conflicts with federal law, or (2) federal law "so thoroughly occupies a legislative field " ' "as to make reasonable the inference that Congress left no room for the States to supplement it." ' [Citation.]" (*Cipollone* v. *Liggett Group, Inc.* (1992) 505 U.S. 504, 516 [112 S.Ct. 2608, 2617, 120 L.Ed.2d 407] (*Cipollone*).) "When Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a 'reliable indicium of congressional intent with respect to state authority' [citation], 'there is no need to infer congressional intent to pre-empt state laws from the substantive provisions' of the legislation. [Citation.]" (*Id.* at p. 517 [112 S.Ct. at p. 2618].)

In this case, Congress enacted an express preemption clause and we only need to "identify the domain expressly pre-empted." (See *Cipollone*, *supra*, 505 U.S. 504, 517 [112 S.Ct. 2608, 2618].) Moreover, we must narrowly read the preemption clause because Proposition 65 is an instance of the state exercising its police power. (*Medtronic*, *supra*, __ U.S. __, __ [116 S.Ct. 2240, 2250]; *Ketchum* v. *Hyundai Motor Co.* (1996) 49 Cal.App.4th 1672, 1678 [57 Cal.Rptr.2d 595].)

Cipollone and Medtronic

The two most recent United States Supreme Court cases to consider preemption are *Cipollone*, *supra*, 505 U.S. 504 and *Medtronic*, *supra*, __ U.S. __ [116 S.Ct. 2240]. Both the People and Cotter contend *Cipollone* supports their position. The Supreme Court decided *Medtronic* while this appeal was pending, and both parties discussed its impact on this appeal at oral argument.

In *Cipollone*, the United States Supreme Court found the amended Public Health Cigarette Smoking Act of 1969 (Smoking Act) preempted common law claims based on a failure to warn about the hazards of smoking, but not those premised on express warranty, intentional fraud and misrepresentation, or conspiracy. (505 U.S. 504 [112 S.Ct. 2608].) The federal statute set forth the exact warning to be placed on each package[7] and the preemption clause specified " '[n]o requirement or prohibition based on smoking and health

[7] The Smoking Act required the following warning: " 'WARNING: THE SURGEON GENERAL HAS DETERMINED THAT CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH.' " (*Cipollone*, *supra*, 505 U.S. at p. 508 [112 S.Ct. at p. 2613].)

shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act.' " (*Id.* at p. 515 [112 S.Ct. at p. 2617].)

When determining whether federal law expressly preempted the common law claims, the court in *Cipollone*, held the following as the central inquiry: "[W]e ask whether the legal duty that is the predicate of the common-law damages action constitutes a 'requirement or prohibition based on smoking and health . . . imposed under State law with respect to . . . advertising or promotion,' giving that clause a fair but narrow reading." (505 U.S. 504, 524 [112 S.Ct. 2608, 2621].) Thus, federal law preempted state claims based on inadequate warnings about health risks.

The United States Supreme Court further refined preemption analysis in *Medtronic, supra*, __ U.S. __ [116 S.Ct. 2240]. In *Medtronic*, the manufacturer of a pacemaker argued the Medical Device Amendments of 1976 (MDA) to the federal Food, Drug and Cosmetics Act governed the requirements for medical devices and its preemption clause prevented the plaintiff's claims of negligence and strict liability based on a defective device and inadequate warnings. (*Id.* at p. __ [116 S.Ct. at p. 2250].) The preemption provision under the MDA provided: "[N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement— [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and [¶] (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." (21 U.S.C. § 360k(a).)

The court in *Medtronic* stated courts should broadly interpret the preemption provision of federal statutes with limited applicability and narrowly interpret those statutes with general applicability. Accordingly, the court in *Cipollone* broadly interpreted the word "requirement" in the preemption provision because: "The pre-emptive statute in *Cipollone* was targeted at a limited set of state requirements—those 'based on smoking and health'—and then only at a limited subset of the possible applications of those requirements—those involving the 'advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of' the federal statute. [Citation.]" (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2252], fn. omitted.)

In contrast to the Smoking Act, the MDA in *Medtronic* applied to all medical devices, warranting a narrow interpretation of "requirement." The

court defined "requirement" under the MDA to include only those situations in which the state and federal government had imposed a conflicting "duty" on the manufacturer. (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2251].) The FDA approved the marketing of the pacemaker in *Medtronic* because it was " 'substantially equivalent' to devices already on the market," and had not specifically evaluated the pacemaker. (*Id.* at p. __ [116 S.Ct. at p. 2248].) Accordingly, the court found the MDA had not issued "any requirement" applicable to this device and it did not preempt the state claim alleging negligent design. (*Id.* at p. __ [116 S.Ct. at p. 2249].)

The court in *Medtronic* also held the MDA did not preempt claims based on inadequate labeling. The MDA required manufacturers of every medical device to include a label containing " 'information for use, . . . and any relevant hazards, contraindications, side effects, and precautions. [Citation.]" (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2256].) The labeling requirements did not apply specifically to the pacemaker; therefore, the court found the federal government had not imposed a labeling "requirement" for the pacemaker.

The court explained why a decision regarding preemption should consider the "generality" of the federal statute: "The generality of those requirements make [*sic*] this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers." (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2258].) Instead, ". . . the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." (*Ibid.*)

When both the state and federal requirements reflect "generic concerns" rather than specific regulations, they probably will not conflict, resulting in no preemption. (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2258].) Preemption occurs "only where a particular state requirement threatens to interfere with a specific federal interest." (*Id.* at p. __ [116 S.Ct. at p. 2257].)

D. *The FHSA, Proposition 65, and Preemption*

(1b) Only one case, *Allenby, supra*, 958 F.2d 941, has reviewed preemption under the FHSA and Proposition 65. It held the FHSA did not preempt Proposition 65.[8]

Cotter argues *Allenby* does not represent good law because it conflicts with the holding in *Cipollone*, contradicts other state and federal decisions made post-*Cipollone*, and ignored and failed to defer to the conclusions of the Consumer Product Safety Commission (CPSC). To support its contention, Cotter cites one other Proposition 65 case in the district court (*Committee of Dental Amalgam Alloy Mfrs.* v. *Henry* (S.D.Cal. 1994) 871 F.Supp. 1278), which was recently reversed in *Stratton, supra*, 92 F.3d 807, and tort claims preempted by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Prior to assessing each of Cotter's criticisms of *Allenby*, we briefly summarize *Allenby*'s analysis of preemption under the FHSA and conduct our own independent analysis of preemption and the FHSA.

1. *Allenby*

When analyzing preemption under the FHSA, the court in *Allenby, supra*, 958 F.2d 941, 946, noted the preemption provision in the FHSA only applies to "cautionary labeling" on packages (15 U.S.C. § 1261 note). The Act defines labels as including accompanying literature only if the material contains "directions for use." (15 U.S.C. § 1261(n).) Thus, if point of sale signs were not "directions for use," they represented a method in which a manufacturer could satisfy Proposition 65 without requiring warning labels in addition to the FHSA.

The court rejected the argument that Proposition 65 warnings "impliedly" direct the consumer to handle the product to "avoid or minimize direct exposure" and were therefore directions for use. (*Allenby, supra*, 958 F.2d 941, 949.) The court explained this was a "nonsensical reading" of the term "directions for use" and it agreed with the lower court's comments during oral argument about a sign stating, " 'this product may cause birth defects.' " The Ninth Circuit quoted the lower court as responding: " '[D]oesn't tell you whether it's going to cause defects if you pour it on your feet, or if you drink it, or if you poke it in your ear, it just says that it may cause birth defects. How is that a direction for use?' " (*Ibid.*) Instead, the court in *Allenby*

[8]*Allenby* also found Proposition 65 was not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act.

determined Congress's intent more likely related to "how much of a deterrent to use, or how long a paint solvent should be mixed."[9] (*Ibid.*)

The court in *Allenby* concluded Proposition 65 did not frustrate any congressional purpose. The FHSA regulates cautionary labeling to promote uniformity but permits the states through the use of point of sale signs to regulate the sale and use of hazardous chemicals. (*Allenby, supra*, 958 F.2d 941, 950.)

2. *Allenby's analysis of labels under the FHSA remains good law post-Cipollone*

(i) *Predicate duty analysis does not apply to general statutes*

3

(4) Cotter argues *Allenby* is not good law because *Cipollone, supra* 505 U.S. 504, 524 [112 S.Ct. 2608, 2621], held the central inquiry for preemption is whether the state and federal statutes have the same predicate duty. Cotter contends Proposition 65 and the FHSA have the same "predicate duty": the legal duty to warn of toxic dangers.

Cotter, however, does not consider the recent decision of *Medtronic*, which explained the predicate duty analysis does not apply when the federal statute merely requires a general duty to inform users and purchasers of potentially dangerous items. (__ U.S. __, __ [116 S.Ct. 2240, 2258].) When the predicate for the plaintiff's claims is the general duty to inform users and purchasers of potentially dangerous items and the federal government has not implemented or enforced specific federal requirements, general obligations imposed by the state do not threaten the federal requirements. (*Ibid.*)

Indeed a recent Ninth Circuit opinion, relying on the analysis of *Medtronic*, held the MDA does not preempt Proposition 65 warnings[10] for

Allenby also found no preemption because the warnings required under Proposition 65 were not "necessarily nonidentical" to the requirements under the FHSA. (958 F.2d at p. 950.) Since neither statute required specific language, a manufacturer could *choose* to use a label which satisfied both Proposition 65 and the FHSA. However, after *Cipollone*, once Congress has enacted a preemption amendment, the issue is not whether the warnings can never be the same, but whether the warnings are identical. The requirements under Proposition 65 are clearly not identical to the warnings under the FHSA. Thus, we disagree with the holding in *Allenby* to the extent it found no preemption on this basis.

[10] Proposition 65 imposed consumer warning requirements for dental amalgam because it contained dental mercury.

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dental amalgam.[11] (*Stratton, supra*, 92 F.3d 807, 810.) "Proposition 65 is a state law of general applicability which was *not* enacted 'with respect to' medical devices." (*Id.* at p. 813.) Rather, "Proposition 65 applies to *all* products and services that pose a health risk to the public." (*Ibid.*) The court concluded: "Thus, we hold that the consumer warning requirement under California's Proposition 65 is not 'specific' enough to trigger preemption because it is 'not the kind[] of requirement[] that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements.' " (*Ibid.*)

Following both *Medtronic* and *Stratton*, the "predicate duty" analysis for preemption does not apply when both the federal and state statutes require a general warning for a variety of products and do not target specific products. As noted above, Proposition 65 is a general statute which applies to all products and services posing a health risk. Similarly, the FHSA is a general statute which requires warnings on labels for substances it determines are hazardous. (15 U.S.C. § 1261.) A " 'hazardous substance' " includes: "Any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition, heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." (15 U.S.C. § 1261(f)(1)(A).)

Given the generality of Proposition 65 and the FHSA, Cotter's criticism of *Allenby* for failing to consider the statutes' predicate duty has no merit. Unlike the Smoking Act in *Cipollone*, which provided requirements for a particular product and specified the exact wording for the warning, the requirements of the FHSA apply to a variety of products in numerous industries. In this situation an analysis of the predicate duty becomes meaningless.

(ii) *Allenby correctly found point of sale signs are not labels*

Allenby's analysis of labels under the FHSA does not contradict the reasoning in either *Cipollone* or *Medtronic*.[12] Our independent examination of Proposition 65 and the FHSA confirms *Allenby*'s finding on point of sale signs and the FHSA.

[11]The two component parts of dental amalgam—dental mercury and amalgam alloy—are separately regulated by the MDA; therefore, the court concluded the MDA covered dental amalgam. (*Stratton, supra*, 92 F.3d 807, 810.)

[12]We express no opinion about *Allenby*'s finding that FIFRA did not preempt Proposition 65 warnings.

(1c) As with any state law regulating health and safety, we begin by presuming Proposition 65 is not displaced. (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2248].) Since the FHSA does have a specific preemption clause, we need to determine "the domain expressly pre-empted." (*Cipollone, supra*, 505 U.S. 504, 517 [112 S.Ct. 2608, 2618].) We determine this "domain" by examining the language of the preemption statute, its " 'statutory framework,' " and the "structure and purpose of the statute as a whole" (*Medtronic, supra*, __ U.S. at p. __ [116 S.Ct. at p. 2251]).

As already stressed, Congress enacted an explicit preemption provision in the FHSA prohibiting a state to establish a cautionary labeling requirement for hazardous substances covered by the FHSA "unless such cautionary labeling requirement is identical to the labeling requirement" in this act. (15 U.S.C. § 1261 note.) The act defines label as a "display of written, printed, or graphic matter upon the immediate container of any substance . . . and (2) on all accompanying literature where there are directions for use, written or otherwise." (15 U.S.C. § 1261(n).)

Congress chose to restrict the definition of a label to include accompanying literature only when that material contains "directions for use." (15 U.S.C. § 1261(n).) These words indicate the warning must tell the user how to use the product. This situation resembles the one in *Medtronic*, where the court refused to interpret "requirement" in the preemption provision of the MDA to mean "remedy" because ". . . if Congress intended to preclude all common-law causes of action, it chose a singularly odd word with which to do it." (*Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2251-2252].) Similarly, if Congress wanted preemption under the FHSA to apply to all accompanying literature with "implied" directions for use, as Cotter argues, Congress could have specified that.

In addition to examining the language of the FHSA, we must consider Congress's stated purpose. The FHSA itself does not contain a section setting forth its purpose but Congress enacted the FHSA in 1960 to " 'provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use.' " (*Moss* v. *Parks Corp.* (4th Cir. 1993) 985 F.2d 736, 739, citing House Com. on Interstate and Foreign Commerce, Federal Hazardous Substances Labeling Act, H.R.Rep. No. 1861, 86th Cong., 2d Sess., p. 2 (1960), reprinted in 1960 U.S. Code Cong. & Admin. News, No. 2, p. 2833.) When Congress amended the FHSA in 1966, the legislative history discussed the impracticality of having the states produce potentially 50 different labels for a particular hazardous substance. (*Jenkins* v. *James B. Day & Co.* (1994) 69 Ohio St.3d 541, 545 [634 N.E.2d 998, 1001-1002].)

To assess Congress's purpose we must also consider the structure and framework of the FHSA. Following *Medtronic, supra*, __ U.S. __, __ [116 S.Ct. 2240, 2250], we must interpret the words in the preemption statute narrowly when the federal statute and state statute have general applicability.

As already stressed, the FHSA is an extremely broad statute. It applies to numerous products in a variety of industries and it does not require specific language on the labels but "merely requires (1) that labels contain the signal word 'WARNING' or 'CAUTION' and (2) words which describe the potential hazard." (*Allenby, supra*, 958 F.2d 941, 950.) Furthermore, the generality of these requirements makes it clear the federal government has not "weighed the competing interests relevant" to the particular hazardous material and has not "reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers" (*Medtronic, supra*, __ U.S. __, __ [1116 S.Ct. 2240, 2258]).

Given the FHSA's general applicability, point of sale signs are unlikely to interfere with the federal government's objectives. Point of sale signs obviously do not require manufacturers to develop more than one label for all 50 states. Moreover, point of sale signs allow the state to regulate sales, a distinctively state interest, without imposing additional labeling requirements on packages. Rather than conflicting with the federal government's objectives, they serve to further the purpose of the FHSA by providing a larger audience with information.

Interpreting Proposition 65's warnings as "implied" direction for use to the consumer to take "steps" to "reduce exposure," as Cotter argues, would create an extensive preemption provision under the FHSA. With such a definition, purely informational signs could be considered implied directions for use. For example, signs merely rating material on the product's appropriateness for minors or adults would constitute labeling. Indeed, price tags could be found to be implied directions for use as one should use expensive items sparingly.

We, therefore, conclude *Allenby* correctly found the FHSA does not preempt Proposition 65 point of sale signs.[13]

[13]The People also argue the FHSA does not preempt Proposition 65 because the state and federal statute warn against different risks. The People contend Proposition 65 addresses harm to the developing fetus (Cal. Code Regs., tit. 22, § 12601, subd. (b)), while the FHSA relates to the risks of chemical pneumonitis, pneumonia, and pulmonary edema caused by aspiration into the lungs and systemic injury from inhaling the vapor. This argument has no merit

3. *Distinguishing FIFRA cases*

To support its argument of preemption, Cotter cites numerous FIFRA cases which found FIFRA preempted common law claims based on inadequate point of sale warnings.[14] (*Taylor AG Industries* v. *Pure-Gro* (9th Cir. 1995) 54 F.3d 555, 560 (*Taylor AG*); *Louisiana-Pacific Corp.* v. *Koppers Co.* (1995) 32 Cal.App.4th 599 [38 Cal.Rptr.2d 257]; *Papas* v. *Upjohn Co.* (11th Cir. 1993) 985 F.2d 516.) Although the preemption provision in FIFRA is essentially identical to the one in the FHSA,[15] that similarity should not obfuscate the differences between the statutes.

Three material differences distinguish FIFRA cases from this case: (1) FIFRA defines a label more expansively than the FHSA; (2) FIFRA is not simply a labeling statute while the FHSA is; and (3) FIFRA cases are predominantly tort common law cases and this is a Proposition 65 enforcement action.

(i) *Differences between the statutes*

FIFRA broadly defines label as the following: "The term 'labeling' means all labels and all other written, printed, or graphic matter— [¶] (A) accompanying the pesticide or device at any time; or [¶] (B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications . . . ." (7 U.S.C. § 136(p)(2).) Congress designated matter "accompanying" the product as a label without any further qualification. Consequently, FIFRA cases do not help us determine Congress's intent when it limited a label under the FHSA to mean accompanying literature providing "directions for use."

More significantly, when examining the "statutory framework" of FIFRA, the differences between the two federal statutes are magnified. Rather than

because, as Cotter asserts, the FHSA includes reproductive toxicity within the meaning of "toxic" (16 C.F.R. § 1500.3(c)(2)(ii)(C) (1996)).

[14]Cotter points out *Burke* v. *Dow Chemical Co.* (E.D.N.Y. 1992) 797 F.Supp. 1128, 1140] (*Burke*) represents the sole post-*Cipollone* case holding FIFRA does not preempt warnings outside of product labeling. The People contend *Burke* correctly applied the "channels of communication" language contained in *Cipollone*. The court in *Cipollone* stated that even if one channel of communication was preempted, other "channels of communication" were not. (*Cipollone*, *supra*, 505 U.S. 504, 528 [112 S.Ct. 2608, 2623].) The court, however, was referring to obligations outside of advertising or the promotion of cigarettes and the statement does not clarify whether labeling includes point of sale signs. Since we find the preemption question under FIFRA and the FHSA to be different, we do not address *Burke*'s interpretation of the court's use of "channels of communication."

[15]FIFRA's preemption clause provides as follows: "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." (7 U.S.C. § 136v(b).)

creating a mere labeling statute, Congress in 1972, "transformed it [FIFRA] into a comprehensive regulatory statute governing the use and sale of pesticides." (*Louisiana-Pacific Corp.* v. *Koppers Co.*, *supra*, 32 Cal.App.4th 599, 603.) One of the cases emphasized by Cotter, *Taylor AG*, *supra*, 54 F.3d 555, 560, noted the "rigorous label-approval process under FIFRA." The court explained: "Although FIFRA does not prescribe the exact contents of labels, manufacturers are not free, . . . to create pesticide labels in any manner they choose. Rather, . . . the EPA approves each label only after a careful review of the product data and the draft label." (*Ibid.*)

Given the statutory framework of FIFRA, a broad interpretation of the word "label" under FIFRA is consistent with *Medtronic*. Not only does FIFRA define "label" expansively, but it represents a situation "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers" (*Medtronic*, *supra*, __ U.S. __, __ [116 S.Ct. 2240, 2258]).

In contrast, as already stressed, the FHSA does not (1) have a label approval process, (2) specify the wording to be used on the label, or (3) regulate the sale or use of the hazardous products covered by the federal statute. Instead, as the People contend, Congress has left the states free to regulate the sale and use of these hazardous products. The FHSA has remained a labeling statute and the scope of its preemption differs significantly from FIFRA.[16] Accordingly, cases interpreting FIFRA have "limited relevance" to determinations of preemption and the FHSA. (See *Jenkins* v. *James B. Day & Co.*, *supra*, 634 N.E.2d 998, 1004, fn. 4.)[17]

(ii) *Differences between tort actions and state enforcement actions*

An additional reason for contending the FIFRA cases cited by Cotter are irrelevant, according to the People, is because they involve tort claims rather than the state's enforcement of a statute. In response, Cotter claims FIFRA

[16]To the extent *Allenby*, *supra*, 958 F.2d 941, 945, held the issue of preemption arising under FIFRA is identical to that under the FHSA, we disagree. We do agree with *Allenby*'s conclusion that the preemption provisions in both statutes are essentially identical.

[17]"Because the FHSA requires no federal agency approval of the precise language which appears on the label of a substance covered by the FHSA, it appears that an inadequate warning claim is more readily preempted for a product covered by FIFRA than would a similar inadequate warning claim be for a product covered by the FHSA. Of course, since this case does not involve FIFRA, we do not resolve this question. We discuss FIFRA merely to explain why cases interpreting that statute may be of limited relevance to the issue in this case." (*Jenkins* v. *James B. Day & Co.*, *supra*, 634 N.E.2d 998, 1004, fn. 4.)

tort cases provide an appropriate method of analysis for federal preemption under the FHSA since the basis for requiring a warning under common law and Proposition 65 is the same. Cotter argues "[w]here the reason is the same, the rule should be the same" (Civ. Code, § 3511), and "[t]he law respects form less than substance" (Civ. Code, § 3528).

As Cotter asserts, enforcement and common law actions pose the same questions and issues in a determination of the "domain expressly preempted." Accordingly, we used *Cipollone* and *Medtronic*, actions in tort, to determine the scope of preemption under the FHSA.

After determining the preempted domain, the analyses of tort and enforcement actions diverge in a materially significant respect. Once the court determines a common law claim falls within the reach of the preemption clause, the analysis ceases. The federal government's interest in promoting interstate commerce always trumps the individual's interests in receiving damages.

Unlike a tort action, an enforcement action requires the court to establish whether any method of compliance with the state statute falls outside the scope of the preemption provision. (See *Stratton*, *supra*, 92 F.3d 807, 810.) If any method is beyond the reach of the preemption provision, the statute remains valid. The federal statute sets the standards for sufficient warnings (barring any tort claims on this basis), but does not necessarily prohibit the state from requiring warnings consistent with the preemption provision that regulate the use and sale of these products.

Both *Allenby*, *supra*, 958 F.2d 941, 948 and *Taylor AG*, *supra*, 54 F.3d 555, 560 acknowledged this distinction when discussing preemption and FIFRA. The Ninth Circuit in *Taylor AG* rejected the argument "that liability should be imposed upon the Manufacturers for failure to warn arising from alleged deficiencies in advertisements, point-of-sale warnings, and other materials distributed in connections with a sale." (54 F.3d at p. 561, fn. omitted.) The court in *Taylor AG* reconciled its holding with the one in *Allenby* by explaining the court in *Allenby* "merely" held "non-label warnings were not preempted by FIFRA," but *Allenby* admitted " '[t]he argument against product liability suits for inadequate labeling is strong.' " (*Taylor AG*, *supra*, at p. 561, fn. 2, quoting *Allenby*, *supra*, at p. 948.)

Cotter claims the two Ninth Circuit cases, *Allenby* and *Taylor AG*, are inconsistent, with the latter representing the better law. However, as both the People and the court in *Taylor AG* point out, the two courts were simply

addressing different types of actions.[18] In finding Proposition 65 is not preempted under the FHSA, because point of sale signs are not labels and do not provide "directions for use," we are not opening the door to common law tort claims premised on the inadequacy of the product label.

Finally, Cotter claims tort actions and enforcement actions are the same because a company must pay a penalty when it violates the statute. The penalty, Cotter claims, has the same consequences as an award for damages. This argument, however, ignores the vital distinction between the two. As the People point out, an enforcement action never requires the court to assess the adequacy of the label, while that is the task facing the court in a tort action. In an enforcement action, the court simply looks to see whether the company has complied with the mandate of the statute.

4. *The CPSC's interpretation of "label" under the FHSA is clearly erroneous*

Cotter contends the court in *Allenby* erred by ignoring the CPSC's conclusion that point of sale signs qualify as a "direction for use." In response to a request from the Chemical Specialties Manufacturers Association for an advisory opinion, Clement D. Earhardt III from the Office of General Counsel of the CPSC concluded on March 6, 1991, the following: "A warning that a product can cause cancer or birth defects is not an express direction for use. Nevertheless, it conveys the information that, in using the product, steps should be taken to minimize or eliminate exposure. Stated another way, the warning itself can also serve as a direction for use." (Advisory Opn. No. 312, p. 3.) The opinion continued: "Therefore, although the warning quoted in your inquiry does not necessarily convey specific actions to be taken in the use of the product, it does convey information about how the product should be used (steps should be taken to reduce exposure). Accordingly, this office views the statement as a direction for use. It follows, therefore, that signs and the like bearing such warnings are 'accompanying literature containing directions for use' and thus are labeling under FHSA § 2(n)."[19] (*Id.* at p. 4.)

The People respond that the defendant in *Allenby* presented this argument and, rather than ignoring it, the court clearly rejected it. Furthermore, the

[18]Dicta in *Taylor AG* suggested the court agreed point of sale signs, even under the broad definition of label in FIFRA, did not constitute labeling. The court stated *Allenby* did not address "whether common law damages could be imposed for the absence of these *non-label* [point of sale signs] warnings." (*Taylor AG, supra*, 54 F.3d 555, 561, fn. 2, italics added.) Thus, it identified point of sale signs as "non-label[s]."

[19]Cotter requests this court to take judicial notice of a letter from CPSC General Counsel Eric A. Rubel dated October 17, 1995, stating Advisory Opinion No. 312 has never been modified, revoked, suspended, or superseded. We grant judicial notice of this letter.

People contend Advisory Opinion No. 312 is not a long-standing administrative application of the statute and is litigation-inspired because it responds to a request during litigation from defense counsel in *Allenby*. Litigation-inspired opinions have no authority (*Bowen* v. *Georgetown University Hospital* (1988) 488 U.S. 204, 212 [109 S.Ct. 468, 473-474, 102 L.Ed.2d 493]), but generally courts have applied this rule only when the administrative agency is a party to the litigation.

The People also claim letters from the general counsel state the March 6, 1991, advisory opinion "did not express a direct opinion on preemption. . . ."[20] Therefore, according to the People, the letter from general counsel is not entitled to deference.

The People's final argument against deferring to the CPSC's advisory opinion is the opinion's interpretation contravenes the language of the statute and regulations. We agree with this assertion and, for the reasons explained fully above, we find the CPSC's interpretation is " 'plainly erroneous' " and entitled to no deference. (*Stinson* v. *U.S.* (1993) 508 U.S. 36 [113 S.Ct. 1913, 1919, 123 L.Ed.2d 598]; *Dix* v. *Superior Court* (1991) 53 Cal.3d 442, 460 [279 Cal.Rptr. 834, 807 P.2d 1063]).

For the foregoing reasons we find point of sale signs pursuant to Proposition 65 do not constitute "directions for use" and are not preempted by the FHSA. We now turn to Cotter's claim of de facto labeling.

II. *Proposition 65 Is Not a De Facto Labeling Statute*

(5) Even if point of sale signs are not labels, Cotter argues Proposition 65 can only be implemented by placing labels on a package; therefore, in practice, it is a labeling statute and preempted by the FHSA. Since the question of de facto labeling raises an issue of law and material fact, we independently review the evidence submitted to determine whether it raises a triable issue of material fact. (*Schrader* v. *Scott*, *supra*, 8 Cal.App.4th 1679, 1684.)

To establish a de facto labeling statute, Cotter must show it can only satisfy the requirements of Proposition 65 by using labels. (*Stratton*, *supra*, 92 F.3d 807, 810 [to find preemption a party must show all possible methods of complying with Proposition 65 conflict with the FHSA].) Cotter cannot

[20]We grant the People's request for judicial notice of letters and other documents from the file of the general counsel of the CPSC. One such letter states "[t]he Commission has not formulated a general view of preemption [of Proposition 65] beyond the express preemption provisions in its various statutes." (Letter dated July 3, 1995, from the general counsel for the CPSC to counsel for Cotter.)

establish de facto labeling merely by demonstrating it is difficult or costly to comply. Rather, it must show using point of sale signs is a "physical impossibility." (See *Allenby, supra*, 958 F.2d 941, 948-949 ["[F]or purposes of preemption analysis," the party arguing preemption must show "a physical impossibility of complying" with both Proposition 65 and the federal statute "before succeeding on a claim that Proposition 65 is preempted on this theory."].)

Cotter cites almost no legal authority to support its contention of de facto labeling, but claims point of sale signs cannot be used because they are ineffective and too expensive to implement. Cotter's evidence of "physical impossibility" amounts to little more than submitting a number of conclusions, declarations, and opinions. Interestingly, Cotter fails to explain why, if point of sale signs are so costly and ineffective in communicating a message, manufacturers continue to use them to advertise their goods.

Cotter first argues the warnings required by Proposition 65 "must be reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure." (Cal. Code Regs., tit. 22, § 12601, subd. (a).) Point of sale signs, he argues, are less effective than product labels in warning consumers. To support this claim he cites a footnote in *King* v. *E.I. Du Pont De Nemours & Co.* ((D.Me. 1992) 806 F.Supp. 1030, 1037, fn. 4]), which was later affirmed in an opinion minus the footnote in *King* v. *E.I. DuPont De Nemours and Co.* ((1st Cir. 1993) 996 F.2d 1346). The footnote merely stated "[w]e can see no more effective way to warn potential users of the dangers of a product than by product labels." (*King* v. *E.I. Du Pont De Nemours & Co., supra*, 806 F. Supp. at p. 1037, fn. 4.) This statement does not establish the ineffectiveness of point of sale signs.

In addition to failing to demonstrate ineffectiveness, Cotter's argument is seriously flawed because a manufacturer does not have to use the best warning method to comply with Proposition 65. The court in *Ingredient Communication Council, Inc.* v. *Lungren* (1992) 2 Cal.App.4th 1480, 1494 [4 Cal.Rptr.2d 216] (*ICC*) confirmed Proposition 65 does not require a manufacturer to use the " 'best' " or most effective method, but merely demands a "reasonable" method. Both the court in *ICC, supra*, 2 Cal.App.4th 1480, 1486 and the safe harbor language set forth in the California Code of Regulations (tit. 22, § 12601, subd. (b)(1)(B)) approve of point of sale signs as a reasonable method.[21]

[21]Cotter argues any method other than labeling would not meet the "reasonableness" test of *ICC, supra*, 2 Cal.App.4th at page 1494. The "reasonableness" test requires the trial court to

Cotter also claims a manufacturer cannot ensure a retailer will properly post the signs without incurring unacceptable costs to implement the program.[22] In support of this argument, Cotter stated it sent signs to its California members on March 1988 and January 1990. Moreover, in January 1994, it sent signs again[23] and directed the members to place both signs "close to each of your own paint factory's products." Cotter also submitted deposition testimony of several retailers explaining the problems they had complying with the manufacturer's requests for them to post point of sale warnings.

To counter Cotter's argument, AYS identified numerous paint and/or adhesive manufacturers complying with Proposition 65 warning signs. Many of True Value Hardware stores did not follow instructions, the People contend, because Cotter did not adequately explain the proper placement of the signs.[24] The People claim once the retailers received explicit instruction about the appropriate location pursuant to the permanent injunction, the majority of those deposed testified they understood the directions and properly complied.[25]

In their final argument, the People maintain Cotter cannot argue de facto labeling because it did not attempt to follow the mandate in *ICC*. The court in *ICC* stated a manufacturer must adjust the warning system in light of operational experience and new facts when attempting to comply with Proposition 65. (*ICC*, *supra*, 2 Cal.App.4th 1480, 1493.) AYS notified Cotter on December 10, 1992, that its stores were not providing warnings for their products containing toluene and Cotter should have taken appropriate steps to remedy the problem. Cotter, the People claim, can exercise a certain level

examine the warning's efficacy and cost before determining whether the warning satisfies Proposition 65. The "reasonableness" test set forth in *ICC*, however, does not apply to point of sale signs. The court in *ICC* limited the "test" to situations in which the trial court had to determine whether "alternative warning methods"—that is, methods outside of the safe harbor warnings—provided a reasonable warning. (*Ibid.*)

[22]Attorneys for the National Paint and Coatings Association filed an amicus curiae brief on behalf of Cotter's de facto labeling argument. Much of the data on the costs associated with point of sale signs is irrelevant to Cotter's inability to use these signs and outside the record.

[23]AYS, an intervener in this action, claims many of these signs did not comply with Proposition 65.

[24]The People contend the directions did not tell retailers to post the signs in front of or next to the spray paints. For example, directions sent January 27, 1992, merely stated: "Signs # 1 and # 2 enclosed should be displayed close to each of your own Paint factory's products."

[25]Cotter insists some retailers did not comply even after being given proper information, establishing manufacturers cannot compel retailers to follow their orders. Cotter, however, misconstrues its burden of proof. It must show it *cannot* comply and, since most retailers did adhere to Cotter's instructions when given the proper information, compliance seems physically possible. As the People point out, Cotter can use a variety of techniques and incentives to encourage acquiescence among the remainder of the retailers.

of control over the True Value stores because members of the cooperative must agree to observe Cotter's bylaws, policies, and procedures.[26]

We find the trial court did not err in finding "Proposition 65 does not impose a de facto labeling requirement on Cotter & Company." Cotter has not established the physical impossibility of meeting Proposition 65 warning requirements with point of sale signs. Cotter may ultimately choose to use a label which complies with both Proposition 65 and the FHSA; however, choosing to use a label does not negate the viability of point of sale signs.

CONCLUSION

The warning requirements of Proposition 65 may be satisfied by point of sale signs which are not "directions for use" or labels under the FHSA. The FHSA, therefore, does not preempt Proposition 65. Additionally, Cotter has failed to prove it cannot use point of sale signs and has not established it cannot use point of sale signs to satisfy Proposition 65 warning requirements. Accordingly, we affirm.

Kline, P. J., and Haerle, J., concurred.

[26]The People claim Cotter could take additional steps to ensure acquiescence. After an action involving Cotter and improper Proposition 65 warnings for methylene chloride paint strippers, the manufacturer remedied the situation by (1) providing clear directions to the stores for the placement of the signs and (2) requiring each store to return a postcard indicating it had properly posted the warning sign. Cotter followed up with phone calls to those stores not returning the postcard.

CALIFORNIA HEALTH AND SAFETY CODE

"(d) To shift the cost of hazardous waste cleanups more onto offenders and less onto law-abiding taxpayers.

"The people hereby enact the provisions of this initiative in furtherance of these rights."

Sections 6, 7 and 8 of Initiative Measure, Nov. 4, 1986, provide:

"Sec. 6. If any provision of this initiative or the application thereof is held invalid, that invalidity shall not affect other provisions or applications of the initiative which can be given effect without the invalid provision or application, and to this end the provisions of this initiative are severable.

"Sec. 7. To further its purposes this initiative may be amended by statute, passed in each house by a two-thirds vote.

"Sec. 8. This initiative shall take effect on January 1, 1987."

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

California's toxics initiative: Making it work. Note, 39 Hast.L.J. 1195 (1988).

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

§ 25249.6. Required warning before exposure to chemicals known to cause cancer or reproductive toxicity

No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual, except as provided in Section 25249.10.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

Law Review Commentaries

Problems with Prop. 65: Will California's toxics initiative hold water? James Dragna, 10 L.A.Law. 18 (April 1987).

Notes of Decisions

Occupational safety and health plan 2
Preemption 1

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1. Preemption

The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C.A. § 136v] did not preempt this section to extent that it merely imposed restrictions on pesticide sale or use, without requiring additions to or deletions from pesticide package labels; many warning methods, including point-of-sale signs currently designated "safe harbor" under this section, could satisfy requirements of California without infringing on federal supremacy in area of pesticide labeling. D-Con Co., Inc. v. Allenby, N.D.Cal.1989, 728 F.Supp. 605.

Principles of comity would not counsel against Court of Appeal's exercising jurisdiction over petition for mandamus ordering state Occupational Safety and Health Standards Board to include in state plan warning and enforcement provisions of this chapter, although manufacturers' association had sought federal declaratory and injunctive relief that this chapter was preempted in the workplace by federal Occupational Safety and Health Act (OSHA) [29 U.S.C.A. § 651 et seq.] because federal hazard communication standard requires employers to warn employees of potential exposure to certain hazardous materials in workplace and state act related to same occupational safety and health issue. California Labor Federation, AFL-CIO v. California Occupational Safety and Health Standards Bd. (App. 1 Dist.1990) 271 Cal.Rptr. 310, 221 Cal.App.3d 1547, review denied.

2. Occupational safety and health plan

Court of Appeal had power to entertain mandamus petition by labor and environmental

Notes of Decisions

Contents of list 1

1. Contents of list

List of "chemicals known to the state to cause cancer or reproductive toxicity" which Governor was required to publish pursuant to this section, is to include, at minimum, both known human and known animal carcinogens and reproductive toxins identified by reference in applicable Labor Code § 6382(b)(1) and (d), despite Governor's argument that list was to include only known human carcinogens and reproductive toxins referred to in Labor Code § 6382(b)(1) and (d). AFL-CIO v. Deukmejian (App. 3 Dist.1989) 260 Cal.Rptr. 479, 212 Cal. App.3d 425.

§ 25249.9. Exemptions from discharge prohibition

(a) Section 25249.5 shall not apply to any discharge or release that takes place less than twenty months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

(b) Section 25249.5 shall not apply to any discharge or release that meets both of the following criteria:

(1) The discharge or release will not cause any significant amount of the discharged or released chemical to enter any source of drinking water.

(2) The discharge or release is in conformity with all other laws and with every applicable regulation, permit, requirement, and order.

In any action brought to enforce Section 25249.5, the burden of showing that a discharge or release meets the criteria of this subdivision shall be on the defendant.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

§ 25249.10. Exemptions from warning requirement

Section 25249.6 shall not apply to any of the following:

(a) An exposure for which federal law governs warning in a manner that preempts state authority.

(b) An exposure that takes place less than twelve months subsequent to the listing of the chemical in question on the list required to be published under subdivision (a) of Section 25249.8.

(c) An exposure for which the person responsible can show that the exposure poses no significant risk assuming lifetime exposure at the level in question for substances known to the state to cause cancer, and that the exposure will have no observable effect assuming exposure at one thousand (1,000) times the level in question for substances known to the state to cause reproductive toxicity, based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of such chemical pursuant to subdivision (a) of Section 25249.8. In

any action brought to enforce Section 25249.6, the burden of showing that an exposure meets the criteria of this subdivision shall be on the defendant.
(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Notes of Decisions

Naturally occurring substances 1

1. Naturally occurring substances

Regulation exempting certain naturally occurring carcinogens and reproductive toxins did not conflict with consumer protection statute requiring clear and reasonable warning before one may lawfully expose person to chemicals which are known to cause cancer or reproductive toxicity. Nicolle-Wagner v. Deukmejian (App. 2 Dist.1991) 281 Cal.Rptr. 494, 230 Cal.App.3d 652, rehearing denied and modified.

Regulation exempting certain naturally occurring carcinogens and reproductive toxins from statutory requirement that warning be given before exposing person to chemicals which are known to cause cancer or reproductive toxicity reasonably effectuated statutory purpose of safeguarding effectiveness of warnings given and removing from regulatory scrutiny those substances which pose only insignificant risk of cancer or birth defects. Nicolle-Wagner v. Deukmejian (App. 2 Dist.1991) 281 Cal.Rptr. 494, 230 Cal.App.3d 652, rehearing denied and modified.

§ 25249.11. Definitions

For purposes of this chapter:

(a) "Person" means an individual, trust, firm, joint stock company, corporation, company, partnership, and association.

(b) "Person in the course of doing business" does not include any person employing fewer than ten employees in his business; any city, county, or district or any department or agency thereof or the state or any department or agency thereof or the federal government or any department or agency thereof; or any entity in its operation of a public water system as defined in Section 4010.1.

(c) "Significant amount" means any detectable amount except an amount which would meet the exemption test in subdivision (c) of Section 25249.10 if an individual were exposed to such an amount in drinking water.

(d) "Source of drinking water" means either a present source of drinking water or water which is identified or designated in a water quality control plan adopted by a regional board as being suitable for domestic or municipal uses.

(e) "Threaten to violate" means to create a condition in which there is a substantial probability that a violation will occur.

(f) "Warning" within the meaning of Section 25249.6 need not be provided separately to each exposed individual and may be provided by general methods such as labels on consumer products, inclusion of notices in mailings to water customers, posting of notices, placing notices in public news media, and the like, provided that the warning accomplished is clear and reasonable. In order to minimize the burden on retail sellers of consumer

products including foods, regulations implementing Section 25249.6 shall to the extent practicable place the obligation to provide any warning materials such as labels on the producer or packager rather than on the retail seller, except where the retail seller itself is responsible for introducing a chemical known to the state to cause cancer or reproductive toxicity into the consumer product in question.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

Amendment of this section by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

§ 25249.12. Implementation

The Governor shall designate a lead agency and such other agencies as may be required to implement the provisions of this chapter including this section. Each agency so designated may adopt and modify regulations, standards, and permits as necessary to conform with and implement the provisions of this chapter and to further its purposes.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

§ 25249.13. Preservation of existing rights, obligations and penalties

Nothing in this chapter shall alter or diminish any legal obligation otherwise required in common law or by statute or regulation, and nothing in this chapter shall create or enlarge any defense in any action to enforce such legal obligation. Penalties and sanctions imposed under this chapter shall be in addition to any penalties or sanctions otherwise prescribed by law.

(Added by Initiative Measure, Nov. 4, 1986, eff. Jan. 1, 1987.)

Historical and Statutory Notes

Purpose and effective date of Initiative Measure, Nov. 4, 1986, see Historical and Statutory Notes under § 25249.5.

§§ 25249.15 to 25249.18. Rejected

Historical and Statutory Notes

Addition of these sections by Stats.1990, c. 407 (Prop. 141) was rejected at the Nov. 6, 1990, general election.

22 CALIFORNIA CODE OF REGULATIONS
§ 12000 ET SEQ.

(1) For the purposes of this section, a chemical is "naturally occurring" if it is a natural constituent of a food, or if it is present in a food solely as a result of absorption or accumulation of the chemical which is naturally present in the environment in which the food is raised, or grown, or obtained; for example, minerals present in the soil solely as a result of natural geologic processes, or toxins produced by the natural growth of fungi.

(2) The "naturally occurring" level of a chemical in a food may be established by determining the natural background level of the chemical in the area in which the food is raised, or grown, or obtained, based on reliable local or regional data.

(3) A chemical is naturally occurring only to the extent that the chemical did not result from any known human activity. Where a food contains a chemical, in part naturally occurring and in part added as a result of known human activity, "exposure" can only occur as to that portion of the chemical which resulted from such human activity. For purposes of this section, "human activity" does not include sowing, planting, irrigation, or plowing or other mechanical preparation of soil for agricultural purposes; but does include the addition of chemicals to irrigation water applied to soil or crops.

(4) Where a chemical contaminant can occur naturally in a food, the chemical is naturally occurring only to the extent that it was not avoidable by good agricultural or good manufacturing practices. The producer, manufacturer, distributor, or holder of the food shall at all times utilize quality control measures that reduce natural chemical contaminants to the "lowest level currently feasible," as this term is used in the Code of Federal Regulations, Title 21, Section 110.110, subdivision (c) (1988).

(b) A person otherwise responsible for an exposure to a listed chemical in a consumer product, other than food, does not "expose" an individual within the meaning of Section 25249.6, to the extent that the person can show that the chemical was a naturally occurring chemical in food, and the food was used in the manufacture, production, or processing of the consumer product. Where a consumer product contains a listed chemical, and the source of the chemical is in part from a naturally occurring chemical in food and in part from other sources, "exposure" can only occur as to that portion of the chemical from other sources.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section refiled 6–19–89 as an emergency; operative 6–22–89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10–20–89. For prior history, see Register 89, No. 10.
2. Emergency Section 12501 repealed 7–10–89; repealer operative 8–9–89. New Section 12501 filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12502. Exposure to a Listed Chemical in Drinking Water.

(a) A person otherwise responsible for an exposure to a listed chemical which involves the use of drinking water, including the use of drinking water in food or any other consumer product, does not "expose" an individual within the meaning of Section 25249.6 to the extent that the person can show that the listed chemical was contained in drinking water which was received from:

(1) a public water system, as defined in Section 4010.1 of the Health and Safety Code;

(2) a commercial supplier of drinking water; or

(3) a source of drinking water in compliance with all applicable primary drinking water standards for all listed chemicals and the chemical in question is the result of treatment of the water in order to achieve compliance with primary drinking water standards.

Where the source of the listed chemical is in part from such drinking water and in part from other sources, "exposure" can occur only as to that portion of the listed chemical from sources other than such drinking water.

(b) For purposes of subdivision (a), the amount of a listed chemical contained in drinking water shall be determined by sampling of the drinking water at the point of delivery and by testing pursuant to Section 12901. If sampling and testing is impractical, the amount of a listed chemical shall be based on test results of the most recent sample of the drinking water taken by the public water system or the commercial drinking water supplier, provided that all sampling and testing has been conducted at the frequency and in the manner required by law, or alternatively, such amount shall be calculated at five percent of the maximum contaminant level set forth in the primary drinking water standard for the listed chemical.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12503. Exposure to Water.

A person otherwise responsible for an exposure to a listed chemical does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in water which the person moved or which was handled in the manner described in Section 12401. Nothing in this section shall be interpreted to affect the responsibility for an exposure which arises from any activity other than that described in Section 12401.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6–19–89 as an emergency; operative 6–22–89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10–20–89. For prior history, see Register 89, No. 10.
2. Emergency Section 12503 repealed 7–10–89; repealer operative 8–9–89. New Section 12503 filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12504. Exposure to Air.

A person otherwise responsible for an exposure to a listed chemical in air does not "expose" an individual within the meaning of Health and Safety Code Section 25249.6 to the extent that the person can show that the listed chemical was contained in air that the person received from the ambient air. Where the source of the listed chemical is in part from the ambient air and in part from other sources, "exposure" does not occur as to that portion of the listed chemical from the ambient air to the extent that the person did not put the listed chemical into the ambient air.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Section 25249.6, Health and Safety Code.

HISTORY

1. New section filed 7–10–89; operative 8–9–89 (Register 89, No. 30).

§ 12505. Miscellaneous.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. New section refiled 6–19–89 as an emergency; operative 6–22–89 (Register 89, No. 30). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10–20–89. For prior history, see Register 89, No. 10.
2. Emergency Section 12505 repealed 7–10–89; repealer operative 8–9–89 (Register 89, No. 30).

Article 6. Clear and Reasonable Warnings

§ 12601. Clear and Reasonable Warnings.

(a) Whenever a clear and reasonable warning is required under section 25249.6 of the Health and Safety Code, the method employed to transmit the warning must be reasonably calculated, considering the alternative

[The next page is 189.]

methods available under the circumstances, to make the warning message available to the individual prior to exposure. The message must clearly communicate that the chemical in question is known to the state to cause cancer, or birth defects or other reproductive harm. Nothing in this section shall be construed to preclude a person from providing warnings other than those specified in subdivisions (b), (c), and (d) which satisfy the requirements of this subdivision, or to require that warnings be provided separately to each exposed individual.

(b) Warnings for consumer products exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed to be clear and reasonable. A "consumer products exposure" is an exposure which results from a person's acquisition, purchase, storage, consumption, or other reasonably foreseeable use of a consumer good, or any exposure that results from receiving a consumer service.

(1) The warning may be provided by using one or more of the following methods singly or in combination:

(A) A warning that appears on a product's label or other labeling. The term "label" means a display of written, printed or graphic matter upon a product or its immediate container. The term "labeling" means any label or other written, printed or graphic matter affixed to or accompanying a product or its container or wrapper.

(B) Identification of the product at the retail outlet in a manner which provides a warning. Identification may be through shelf labeling, signs, menus, or a combination thereof.

(C) A system of signs, public advertising identifying the system and toll-free information services, or any other system, that provides clear and reasonable warnings.

(D) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

1. Primarily intended for consumption off the premises where sold or distributed:

(i) at least one notice or sign, no smaller than 10 inches wide by 10 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(ii) at least one horizontal strip marker no smaller than 10 1/2 inches wide by 1 1/4 inches high, and bearing the warning message set forth in paragraph (4)(E) of this subsection; or

(iii) a notice no smaller than 5 inches by 5 inches, and bearing the warning message set forth in (4)(E) of this subsection.

(iv) If signs 10 inches high by 10 inches wide are used, the word "warning" shall be centered three-quarters of an inch from the top of the sign in ITC Garamond bold condensed type face all in one-inch capital letters. Three-sixteenths of an inch from the base of the word "warning" shall be a line extending from left to right across the width of the sign one-sixteenth of an inch in thickness. Centered one-half inch below the line shall be the body of the warning message in 36/50 ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. For the body of the warning message, left and right margins of at least one-half of an inch, and a bottom margin of at least one-half inch shall be observed. Larger signs shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide.

(v) If the 10 1/2 inch by 1 1/4 inch horizontal strip markers are used, the word "WARNING," punctuated by a colon, shall be justified left and located three-sixteenths of an inch from the top of the strip notice in ITC Garamond bold condensed type face all in capital letters measuring eleven sixteenths of an inch in height. Three thirty-seconds of an inch from the base of the word "WARNING" shall be a line extending from left to right across the width of the word "WARNING" and the punctuating colon one thirty-second of an inch in thickness. Located one-fourth of an inch from the top and one-fourth of an inch from the bottom of the strip notice, and to the immediate right of the word "WARNING," shall be the body of the warning message in 12/16 point ITC Garamond bold condensed type face with the initial letter of each word, other than the conjunctive "and," capitalized. The word "WARNING" shall be one-half inch from the left edge of the strip notice and the requisite warning message shall extend to within one-half inch from the right edge.

(vi) If the 5 inch by 5 inch signs are used, they shall bear substantially the same proportions of type size and spacing to sign dimension as the sign 10 inches high by 10 inches wide, with both the word "WARNING" and the warning text set in white on a contrasting red background.

(vii) Such sign or notice shall be placed in the retail establishment so as to assure that it is readable and likely to be read either at each retail point of sale or each point of display. Such sign or notice shall be placed either at all retail points of sale or all points of display, but need not be placed at both. If 10 inch by 10 inch signs or notices are placed at the point of display, each shall be placed no more than ten feet from any alcoholic beverage container and in a manner associating the sign or notice with the display. If horizontal strip notices are used, they shall be placed at ten foot intervals horizontally along the display. If a 5 inch by 5 inch sign is used, it shall be conspicuously placed at each retail point of sale (e.g., checkout counter, cash register, cash box) so that it is likely to be read and understood during the sales transaction.

(viii) All measurements specified or referred to in paragraphs (iv), (v) and (vi), above, are not required to be precisely accurate.

2. Provided for consumption on the premises at tables served by food or beverage persons, or sold or distributed through over the counter service:

(i) a notice or sign displayed at each of the tables where alcoholic beverages are served or may be consumed at least 5 inches high by 5 inches wide bearing substantially the same type face and substantially the same proportion of type size and spacing to sign dimension as described in paragraph (D)1. (vi); or

(ii) the warning message set forth in paragraph (4)(E) of this subdivision, placed upon a menu or list in association with the alcoholic beverages listed thereon and served at such premises, or if alcoholic beverages are not listed thereon, on any menu or list provided to patrons in association with the listing of food or beverage offerings, in type size and design, such that the text is conspicuous and likely to be read prior to consumption of alcoholic beverages or,

(iii) at least one 10 inch by 10 inch sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed so that it is readable and likely to be read by patrons as they enter each public entrance to the establishment. If the establishment does not have clearly defined physical boundaries delineating those areas where, by permit or license, alcoholic beverages are served, the 10 inch by 10 inch sign shall be posted so that it is readable and likely to be read by patrons as they enter the area or areas where, by permit or license, alcoholic beverages are served; and

(iv) If sold or distributed through over-the-counter service, at least one sign, meeting the specifications set forth in paragraph (D)1. (iv) of this subsection, placed in the retail establishment so that the warning message is, prior to the consumption of alcoholic beverages, readable and likely to be read from all counter locations available to the public. Therefore, a retail establishment providing a warning pursuant to the preceding sentence, also would be required to provide a warning in accordance with either paragraph 2.(i), 2.(ii) or 2.(iii) of this subsection.

3. For premises which are specially licensed to sell and serve alcoholic beverages both on and off the licensed premises (e.g., in facilities that offer both "tasting" and retail sales), the off-sale portion of the premises shall comply with the provisions of subsection (D)1, above, and the portion of the premises where alcoholic beverages are served shall comply with the provisions of subsection (D)2, above.

4. For alcoholic beverages sold or distributed to consumers through the mail or package delivery services, warnings may be provided by incorporating or placing the warning message set forth in paragraph (4)(E) on or in the shipping container or delivery package in such a manner so that the warning message is likely to be read by the recipient prior to consumption of the alcoholic beverage(s).

3. All signs or notices referred to in subsections (D)1., (D)2. and (D)3., above, shall be displayed so that they are clearly visible under all lighting conditions normally encountered during business hours.

(2) To the extent practicable, warning materials such as signs, notices, menu stickers, or labels shall be provided by the manufacturer, producer, or packager of the consumer product, rather than by the retail seller. For alcoholic beverages, the placement and maintenance of the warning shall be the responsibility of the manufacturer or its distributor at no cost to the retailer, and any consequences for failure to do the same shall rest solely with the manufacturer or its distributor, provided that the retailer does not remove, deface, or obscure the requisite signs or notices, or obstruct, interfere with, or otherwise frustrate the manufacturer's reasonable efforts to post, maintain, or periodically replace said materials. For prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning.

(3) The warnings provided pursuant to paragraphs (1)(A) and (1)(B) shall be prominently placed upon a product's label or other labeling or displayed at the retail outlet with such conspicuousness, as compared with other words, statements, designs, or devices in the label, labeling or display as to render it likely to be read and understood by an ordinary individual under customary conditions of purchase or use.

(4) The warning message must include the following language:

(A) For consumer products that contain a chemical known to the state to cause cancer:

"WARNING: This product contains a chemical known to the State of California to cause cancer."

(B) For consumer products that contain a chemical known to the state to cause reproductive toxicity:

"WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(C) For food, other than alcoholic beverages, sold, served, or otherwise provided in food facilities, as defined in Health and Safety Code section 27521(a), which is intended for immediate consumption:

"WARNING: Chemicals known to the State of California to cause cancer, or birth defects or other reproductive harm may be present in foods or beverages sold or served here."

(D) For fresh fruits, nuts and vegetables:

"WARNING: This product may contain a chemical known to the State of California to cause cancer, or birth defects or other reproductive harm."

(E) For alcoholic beverages, including, without limitation, beer, malt beverages, wine and distilled spirits:

"WARNING: Drinking Distilled Spirits, Beer, Coolers, Wine and Other Alcoholic Beverages May Increase Cancer Risk, and, During Pregnancy, Can Cause Birth Defects."

(5) A person in the course of doing business, who manufactures, produces, assembles, processes, handles, distributes, stores, sells or otherwise transfers a consumer product which he or she knows to contain a chemical known to the state to cause cancer or reproductive toxicity in an amount which requires a warning shall provide a warning to any person to whom the product is sold or transferred unless the product is packaged or labeled with a clear and reasonable warning.

(c) Warnings for occupational exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "occupational exposure" is an exposure, in the workplace of the employer causing the exposure, to any employee.

(1) The method employed to transmit the warning must include one of the following alternative methods:

(A) A warning that appears on the label or labeling of a product or substance present or used in the workplace. The label or labeling shall be prominently displayed on the product or substance and the product or substance shall be used under circumstances which make it likely that the warnings will be read and understood by employees or other individuals prior to the exposure for which the warning is given.

(B) A warning that appears on a sign in the workplace posted in a conspicuous place and under conditions that make it likely to be read and understood by employees and other individuals prior to the exposure for which the warning is given.

(C) A warning to the exposed employee about the chemical in question which fully complies with all information, training and labeling requirements of the federal Hazard Communication Standard (29 CFR section 1910.1200, as amended and filed September 30, 1986), the California Hazard Communication Standard (Cal. Code Regs., title 8, section 5194, as amended and filed May 26, 1987), or, for pesticides, the Pesticides and Worker Safety requirements (Cal. Code Regs., title 3, ch. 6, subch. 3, group 3, section 6700 et seq., in effect on February 16, 1988) authorized in Food and Agricultural Code section 12981 (as amended by Statutes of 1980, ch. 926, p. 2945, section 1).

(2) For purposes of paragraph (1)(A) of this subdivision, the warning shall be provided in terms which would provide a clear warning for a consumer product as specified above.

(3) For purposes of paragraph (1)(B) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

(d) Warnings for environmental exposures which include the methods of transmission and the warning messages as specified by this subdivision shall be deemed clear and reasonable. An "environmental exposure" is an exposure which may foreseeably occur as the result of contact with an environmental medium, including, but not limited to, ambient air, indoor air, drinking water, standing water, running water, soil, vegetation, or manmade or natural substances, either through inhalation, ingestion, skin contact or otherwise. Environmental exposures include all exposures which are not consumer products exposures, or occupational exposures.

(1) The method employed to transmit the warning must include the most appropriate of the following alternative methods under the circumstances:

(A) A warning that appears on a sign in the affected area. The term "sign" means a presentation of written, printed or graphic matter. The term "affected area" means the area in which an exposure to a chemical known to the state to cause cancer or reproductive toxicity is at a level that requires a warning. A posting of signs in the manner described in section 6776(e)(1) of title 3 of the California Code of Regulations (as amended and filed August 15, 1986) shall be sufficient for purposes of this paragraph.

(B) A warning which is in a notice mailed or otherwise delivered to each occupant in the affected area. Such notice shall be provided at least once in any three-month period.

(C) A warning provided by public media announcements which target the affected area. Such announcements shall be made at least once in any three-month period.

(2) Environmental exposure warnings shall be provided in a conspicuous manner and under such conditions as to make it likely to be read, seen or heard and understood by an ordinary individual in the course of normal daily activity, and reasonably associated with the location and source of the exposure.

(3) For purposes of paragraph (1)(A) of this subdivision, the following specific warning messages shall be deemed to clearly communicate that

an individual is being exposed to a chemical known to the state to cause cancer, or birth defects or other reproductive harm.

(A) For exposure to a chemical known to the state to cause cancer:

"WARNING: This area contains a chemical known to the State of California to cause cancer."

(B) For exposure to a chemical known to the state to cause reproductive toxicity:

"WARNING: This area contains a chemical known to the State of California to cause birth defects or other reproductive harm."

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.6 and 25249.11, Health and Safety Code.

HISTORY

1. Amendment of subsection (b) filed 6-7-89 as an emergency; operative 7-1-89 (Register 89, No. 24). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-30-89. For prior history, see Register 88, No. 53.
2. Certificate of Compliance as to 6-7-89 order transmitted to OAL 10-23-89 and filed 11-22-89 (Register 89, No. 48).
3. Editorial correction of printing error in subsection (c)(1)(C) (Register 91, No. 31).

Article 7. No Significant Risk Levels

§ 12701. General.

(a) The determination of whether a level of exposure to a chemical known to the state to cause cancer poses no significant risk for purpose of Health and Safety Code Section 25249.10(c) shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the listing of the chemical as known to the state to cause cancer. Nothing in this article shall preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk.

(b) A level of exposure to a listed chemical, assuming daily exposure at that level, shall be deemed to pose no significant risk provided that the level is determined:

(1) By means of a quantitative risk assessment that meets the standards described in Section 12703;

(2) By application of Section 12707 (Routes of Exposure); or

(3) By one of the following, as applicable:

(A) If a specific regulatory level has been established for the chemical in question in Section 12705, by application of that level.

(B) If no specific level is established for the chemical in question in Section 12705, by application of Section 12709 (Exposure to Trace Elements) or 12711 (Levels Based on State or Federal Standards) unless otherwise provided.

(c) The chemicals, routes of exposure and conditions of use specifically listed in this article do not include all chemicals, routes of exposure and conditions of use that pose no significant risk. The fact that a chemical, route of exposure or condition of use does not appear in this article does not mean that it poses a significant risk.

(d) This article establishes exposure levels posing no significant risk solely for purposes of Health and Safety Code Section 25249.10(c). Nothing in this article shall be construed to establish exposure or risk levels for other regulatory purposes.

NOTE: Authority cited: Section 25249.12, Health and Safety Code. Reference: Sections 25249.5, 25249.6, 25249.9, 25249.10 and 25249.11, Health and Safety Code.

HISTORY

1. New section filed 3-24-88 as an emergency; operative 3-27-88 (Register 88, No. 11). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-27-88.
2. New section refiled 6-27-88 as an emergency; operative 6-27-88 (Register 88, No. 27). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 10-25-88.
3. New section refiled 10-17-88 as an emergency; operative 10-25-88 (Register 88, No. 44). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 2-23-89.
4. New section refiled 2-21-89 as an emergency; operative 2-23-89 (Register 89, No. 10). A Certificate of Compliance must be transmitted to OAL within 120 days or emergency language will be repealed on 6-23-89.
5. Certificate of Compliance including amendment transmitted to OAL 6-9-89 and filed 7-10-89 (Register 89, No. 30).
6. Amendment of subsection (b)(3)(B) filed 11-16-93; operative 12-16-93 (Register 93, No. 47).

§ 12703. Quantitative Risk Assessment.

(a) A quantitative risk assessment which conforms to this section shall be deemed to determine the level of exposure to a listed chemical which, assuming daily exposure at that level, poses no significant risk. The assessment shall be based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for listing the chemical as known to the state to cause cancer. In the absence of principles or assumptions scientifically more appropriate, based upon the available data, the following default principles and assumptions shall apply in any such assessment:

(1) Animal bioassay studies for quantitative risk assessment shall meet generally accepted scientific principles, including the thoroughness of experimental protocol, the degree to which dosing resembles the expected manner of human exposure, the temporal exposure pattern, the duration of study, the purity of test material, the number and size of exposed groups, the route of exposure, and the extent of tumor occurrence.

(2) The quality and suitability of available epidemiologic data shall be appraised to determine whether the study is appropriate as the basis of a quantitative risk assessment, considering such factors as the selection of the exposed and reference groups, reliable ascertainment of exposure, and completeness of follow-up. Biases and confounding factors shall be identified and quantified.

(3) Risk analysis shall be based on the most sensitive study deemed to be of sufficient quality.

(4) The results obtained for the most sensitive study deemed to be of sufficient quality shall be applicable to all routes of exposure for which the results are relevant.

(5) The absence of a carcinogenic threshold dose shall be assumed and no-threshold models shall be utilized. A linearized multistage model for extrapolation from high to low doses, with the upper 95 percent confidence limit of the linear term expressing the upper bound of potency shall be utilized. Time-to-tumor models may be appropriate where data are available on the time of appearance of individual tumors, and particularly when survival is poor due to competing toxicity.

(6) Human cancer potency shall be derived from data on human or animal cancer potency. Potency shall be expressed in reciprocal milligrams of chemical per kilogram of bodyweight per day. Interspecies conversion of animal cancer potency to human cancer potency shall be determined by multiplying by a surface area scaling factor equivalent to the ratio of human to animal bodyweight, taken to the one-third power. This is equivalent to a scaling factor of 14 when extrapolating from mouse data, and a scaling factor of 6.5 when extrapolating from rat data.

(7) When available data are of such quality that physiologic, pharmacokinetic and metabolic considerations can be taken into account with confidence, they may be used in the risk assessment for inter-species, inter-dose, and inter-route extrapolations.

(8) When the cancer risk applies to the general population, human body weight of 70 kilograms shall be assumed. When the cancer risk applies to a certain subpopulation, the following assumptions shall be made, as appropriate:

Subpopulation	*Kilograms of Body Weight*
Man (18+ years of age)	70
Woman (18+ years of age)	58
Woman with conceptus	58
Adolescent (11-18 years of age)	40
Child (2-10 years of age)	20
Infant (0-2 years of age)	10

(b) For chemicals assessed in accordance with this section, the risk level which represents no significant risk shall be one which is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question, except where sound

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class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) Label and labeling

(1) Label

The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) Labeling

The term "labeling" means all labels and all other written, printed, or graphic matter—

(A) accompanying the pesticide or device at any time; or

(B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.

(q) Misbranded

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 136w(c)(3) of this title;

(C) it is an imitation of, or is offered for sale under the name of, another pesticide;

(D) its label does not bear the registration number assigned under section 136e of this title to each establishment in which it was produced;

(E) any word, statement, or other information required by or under authority of this subchapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment; or

(H) in the case of a pesticide not registered in accordance with section 136a of this title and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(A) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

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the above-named dosages or concentrations, the human data shall take precedence.

(i) The term "corrosive" means any substance which in contact with living tissue will cause destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces.

(j) The term "irritant" means any substance not corrosive within the meaning of subparagraph (i) of this section which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction.

(k) The term "strong sensitizer" means a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Secretary. Before designating any substance as a strong sensitizer, the Secretary, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity.

(*l*)(1) The terms "extremely flammable", "flammable", and "combustible" as applied to any substance, liquid, solid, or the content of a self-pressurized container shall be defined by regulations issued by the Commission.

(2) The test methods found by the Commission to be generally applicable for defining the flammability or combustibility characteristics of any such substance shall also be specified in such regulations.

(3) In establishing definitions and test methods related to flammability and combustibility, the Commission shall consider the existing definitions and test methods of other Federal agencies involved in the regulation of flammable and combustible substances in storage, transportation and use; and to the extent possible, shall establish compatible definitions and test methods.

(4) Until such time as the Commission issues a regulation under paragraph (1) defining the term "combustible" as applied to liquids, such term shall apply to any liquid which has a flash point above eighty degrees Fahrenheit to and including one hundred and fifty degrees, as determined by the Tagliabue Open Cup Tester.

(m) The term "radioactive substance" means a substance which emits ionizing radiation.

(n) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any substance or, in the case of an article which is unpackaged or is not packaged in an immediate container intended or suitable for delivery to the ultimate consumer, a display of such matter directly upon the article involved or upon a tag or other suitable material affixed thereto; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears (1) on the outside container or wrapper, if any there be, unless it is easily legible through the outside container or wrapper and (2) on all accompanying literature where there are directions for use, written or otherwise.

(o) The term "immediate container" does not include package liners.

(p) The term "misbranded hazardous substance" means a hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title or if such substance, except as otherwise provided by or pursuant to section 1262 of this title, fails to bear a label—

(1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (C) the signal word "DANGER" on substances which are extremely flammable, corrosive, or highly toxic; (D) the signal word "WARNING" or "CAUTION" on all other hazardous substances; (E) an affirmative statement of the principal hazard or hazards, such as "Flammable", "Combustible", "Vapor Harmful", "Causes Burns", "Absorbed Through Skin", or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary pursuant to section 1262 of this title; (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word "poison" for any hazardous substance which is defined as "highly toxic" by subsection (h) of this section; (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) "Keep out of the reach of children" or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

(2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast by typography, layout, or color with other printed matter on the label.

The term "misbranded hazardous substance" also includes a household substance as defined in section 1471(2)(C) of this title if it is a substance described in paragraph (1) of subsection (f) of this section and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 1472 or 1473 of this title.

(q)(1) The term "banned hazardous substance" means (A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Secretary by regulation classifies as a "banned hazardous substance" on the basis of a finding that, notwith-

repealing sections 401 to 411 of this title] is declared unconstitutional, or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby."

Transfer of Functions. Functions of the Secretary of Health, Education, and Welfare under this chapter transferred to the Consumer Product Safety Commission, see section 2079 of this title.

The Atomic Energy Commission was abolished and all functions were transferred to the Administrator of the Energy Research and Development Administration (unless otherwise specifically provided) by section 5814 of Title 42, The Public Health and Welfare. The Energy Research and Development Administration was terminated and functions vested by law in the Administrator thereof were transferred to the Secretary of Energy (unless otherwise specifically provided) by sections 7151(a) and 7293 of Title 42.

Effect upon Federal and State Law. Pub. L. 86–613, § 18, formerly 17, July 12, 1960, 74 Stat. 380, as amended Pub.L. 89–756, § 4 (a), Nov. 3, 1966, 80 Stat. 1305; renumbered and amended Pub.L. 91–113, § 4(a), (b)(1), Nov. 6, 1969, 83 Stat. 189, 190; Pub.L. 94–284, § 17(a), May 11, 1976, 90 Stat. 510, provided that:

"(a) Nothing in this Act [adding this chapter and repealing sections 401 to 411 of this title] shall be construed to modify or affect the provisions of the Flammable Fabrics Act, as amended (15 U.S.C. 1191 to 1200) [sections 1191 to 1200 of this title], or any regulations promulgated thereunder; or of chapter 39, title 18, United States Code, as amended (18 U.S.C. 831 et seq.) [section 831 et seq. of Title 18], or any regulations promulgated thereunder or under sections 204(a)(2) and 204(a)(3) of the Interstate Commerce Act, as amended [section 304(a)(2), (3) of Title 49] (relating to the transportation of dangerous substances and explosives by surface carriers); or of section 1716, title 18, United States Code [section 1716 of Title 18], or any regulations promulgated thereunder (relating to mailing of dangerous substances); or of section 902 [section 1472 of Title 49] or regulations promulgated under section 601 of the Federal Aviation Act of 1958 [section 1421 of Title 49] (relating to transportation of dangerous substances and explosives in aircraft); or of the Federal Food, Drug, and Cosmetic Act [chapter 9 of Title 21]; or of the Public Health Service Act [chapter 6A of Title 42]; or of the Federal Insecticide, Fungicide, and Rodenticide Act [section 135 et seq. of Title 7]; or of the Dangerous Drug Act for the District of Columbia (70 Stat. 612), or the Act entitled 'An Act to regulate the practice of pharmacy and the sale of poisons in the District of Columbia, and for other purposes', approved May 7, 1906 (34 Stat. 175), as amended; or of any other Act of Congress, except as specified in section 19 [set out as a note under former sections 401 to 411 of this title].

"(b)(1)(A) Except as provided in paragraphs (2) and (3), if a hazardous substance or its packaging is subject to a cautionary labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title] designed to protect against a risk of illness or injury associated with the substance, no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement applicable to such substance or packaging and designed to protect against the same risk of illness or injury unless such cautionary labeling requirement is identical to the labeling requirement under section 2(p) or 3(b) [subsec. (p) of this section or section 1262(b) of this title].

"(B) Except as provided in paragraphs (2), (3), and (4), if under regulations of the Commission promulgated under or for the enforcement of section 2(q) [subsec. (q) of this section] a requirement is established to protect against a risk of illness or injury associated with a hazardous substance, no State or political subdivision of a State may establish or continue in effect a requirement applicable to such substance and designed to protect against the same risk of illness or injury unless such requirement is identical to the requirement established under such regulations.

"(2) The Federal Government and the government of any State or political subdivision of a State may establish and continue in effect a requirement applicable to a hazardous substance for its own use (or to the packaging of such a substance) which requirement is designed to protect against a risk of illness or injury associated with such substance and which is not identical to a requirement described in paragraph (1) applicable to such substance (or packaging) and designed to protect against the same risk of illness or injury if the Federal, State, or political subdivision requirement provides a higher degree of protection from such risk of illness or injury than the requirement described in paragraph (1).

"(3)(A) Upon application of a State or political subdivision of a State, the Commission may, by regulation promulgated in accor-

(2) Proceedings for the issuance, amendment, or repeal of regulations under this subsection and the admissibility of the record of such proceedings in other proceedings, shall in all respects be governed by the provisions of section 371(e), (f), and (g) of Title 21, except that—

(A) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 348(f)(2) of Title 21; and

(B) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3) of section 348(g) of Title 21.

Reasonable variations or additional label requirements

(b) If the Secretary finds that the requirements of section 1261 (p)(1) of this title are not adequate for the protection of the public health and safety in view of the special hazard presented by any particular hazardous substance, he may by regulation establish such reasonable variations or additional label requirements as he finds necessary for the protection of the public health and safety; and any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children, which fails to bear a label in accordance with such regulations shall be deemed to be a misbranded hazardous substance.

Exemption from requirements by regulation

(c) If the Secretary finds that, because of the size of the package involved or because of the minor hazard presented by the substance contained therein, or for other good and sufficient reasons, full compliance with the labeling requirements otherwise applicable under this chapter is impracticable or is not necessary for the adequate protection of the public health and safety, the Secretary shall promulgate regulations exempting such substance from these requirements to the extent he determines to be consistent with adequate protection of the public health and safety.

Exemption from requirements of this chapter of substances or containers adequately regulated by other provisions of law

(d) The Secretary may exempt from the requirements established by or pursuant to this chapter any hazardous substance or container of a hazardous substance with respect to which he finds that adequate requirements satisfying the purposes of this chapter have been established by or pursuant to any other Act of Congress.

Regulation of toys or articles intended for use by children

(e)(1) A determination by the Secretary that a toy or other article intended for use by children presents an electrical, mechanical, or thermal hazard shall be made by regulation in accordance with the procedures prescribed by section 553 (other than clause (B) of the last sentence of subsection (b) of such section) of Title 5 unless the Secretary elects the procedures prescribed by subsection (e) of section 371 of Title 21, in which event such subsection and subsections (f) and (g) of such section 371 of Title 21 shall apply to the making of such determination. If the Secretary makes such election, he

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product, but by all others in a household, especially children.

(8) The definition of "radioactive substance" in section 2(m) of the act (restated in paragraph (b)(11) of this section) is supplemented by the following: *Radioactive substance* means a substance which, because of nuclear instability, emits electromagnetic and/or particulate radiation capable of producing ions in its passage through matter. Source materials, special nuclear material, and byproduct materials described in section 2(f)(3) of the act are exempt.

(9) In the definition of "label" in section 2(n) of the act (restated in paragraph (b)(12) of this section), a provision stipulates that words, statements, or other information required to be on the label must also appear on all accompanying literature where there are directions for use, written or otherwise. To make this provision more specific, "accompanying literature" is interpreted to mean any placard, pamphlet, booklet, book, sign, or other written, printed, or graphic matter or visual device that provides directions for use, written or otherwise, and that is used in connection with the display, sale, demonstration, or merchandising of a hazardous substance intended for or packaged in a form suitable for use in the household or by children.

(10) The definition of "misbranded hazardous substance" in section 2(p) of this act (restated in paragraph (b)(14) of this section) is supplemented by the following definitions or interpretations of terms used therein:

(i) *Hazardous substances intended, or packaged in a form suitable, for use in the household* means any hazardous substance, whether or not packaged, that under any customary or reasonably foreseeable condition of purchase, storage, or use may be brought into or around a house, apartment, or other place where people dwell, or in or around any related building or shed including, but not limited to, a garage, carport, barn, or storage shed. The term includes articles, such as polishes or cleaners, designed primarily for professional use but which are available in retail stores, such as hobby shops, for nonprofessional use. Also included are items, such as antifreeze and radiator cleaners, that although principally for car use may be stored in or around dwelling places. The term does not include industrial supplies that might be taken into a home by a serviceman. An article labeled as, and marketed solely for, industrial use does not become subject to this act because of the possibility that an industrial worker may take a supply for his own use. Size of unit or container is not the only index of whether the article is suitable for use in or around the household; the test shall be whether under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling.

(ii) *Conspicuously* in section 2(p)(1) of the act and *prominently* and *conspicuous* in section 2(p)(2) of the act mean that, under customary conditions of purchase, storage, and use, the required information shall be visible, noticeable, and in clear and legible English. Some factors affecting a warning's prominence and conspicuousness are: Location, size of type, and contrast of printing against background. Also bearing on the effectiveness of a warning might be the effect of the package contents if spilled on the label.

NOTE: The definitions of *extremely flammable, flammable,* and *combustible* hazardous substances set forth above in paragraphs (b)(10) and (c)(6) are effective August 10, 1987. The definitions remaining in effect until August 10, 1987, as published at 38 FR 27012, Sept. 27, 1973, and amended at 38 FR 30105, Nov. 1, 1973, are set forth below. Manufacturers and labelers of products subject to the Federal Hazardous Substances Act may continue to use these definitions for labeling of those products under the conditions set forth in §1500.3(c)(6)(iv), as amended.

(b)(10) *Extremely flammable* shall apply to any substance which has a flashpoint at or below 20 °F. as determined by the Tagliabue Open Cup Tester; *flammable* shall apply to any substance which has a flashpoint of above 20 °F., to and including 80 °F., as determined by the Tagliabue Open Cup Tester; and *combustible* shall apply to any substance which has a flashpoint above 80 °F. to and including 150 °F., as determined by the Tagliabue Open Cup Tester; except that the flammability or combustibility of solids and of the contents of self-pressurized containers shall be determined by methods found

§ 1500.14 Products requiring special labeling under section 3(b) of the act.

(a) Human experience, as reported in the scientific literature and to the Poison Control Centers and the National Clearing House for Poison Control Centers, and opinions of informed medical experts establish that the following substances are hazardous:

(1) Diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol.

(2) Ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol.

(3) Products containing 5 percent or more by weight of benzene (also known as benzol) and products containing 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates such as kerosine, mineral seal oil, naphtha, gasoline, mineral spirits, stoddard solvent, and related petroleum distillates.

(4) Methyl alcohol (methanol) and mixtures containing 4 percent or more by weight of methyl alcohol (methanol).

(5) Turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and mixtures containing 10 percent or more by weight of such turpentine.

(b) The Commission finds that the following substances present special hazards and that, for these substances, the labeling required by section 2(p)(1) of the act is not adequate for the protection of the public health. Under section 3(b) of the act, the following specific label statements are deemed necessary to supplement the labeling required by section 2(p)(1) of the act:

(1) *Diethylene glycol.* Because diethylene glycol and mixtures containing 10 percent or more by weight of diethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word "warning" and the statement "Harmful if swallowed."

(2) *Ethylene glycol.* Because ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol are commonly marketed, stored, and used in a manner increasing the possibility of accidental ingestion, such products shall be labeled with the signal word "warning" and the statement "Harmful or fatal if swallowed."

(3) *Benzene, toluene, xylene, petroleum distillates.* (i) Because inhalation of the vapors of products containing 5 percent or more by weight of benzene may cause blood dyscrasias, such products shall be labeled with the signal word "danger," the statement of hazard "Vapor harmful," the word "poison," and the skull and crossbones symbol. If the product contains 10 percent or more by weight of benzene, it shall bear the additional statement of hazard "Harmful or fatal if swallowed" and the additional statement "Call physician immediately."

(ii) Because products containing 10 percent or more by weight of toluene, xylene, or any of the other substances listed in paragraph (a)(3) of this section may be aspirated into the lungs, with resulting chemical pneumonitis, pneumonia, and pulmonary edema, such products shall be labeled with the signal word "danger," the statement or hazard "Harmful or fatal if swallowed," and the statement "Call physician immediately."

(iii) Because inhalation of the vapor of products containing 10 percent or more by weight of toluene or xylene may cause systemic injury, such products shall bear the statement of hazard "Vapor harmful" in addition to the statements prescribed in paragraph (b)(3)(ii) of this section.

(4) *Methyl alcohol (methanol).* Because death and blindness can result from the ingestion of methyl alcohol, the label for this substance and for mixtures containing 4 percent or more by weight of this substance shall include the signal word "danger," the additional word "poison," and the skull and crossbones symbol. The statement of hazard shall include "Vapor harmful" and "May be fatal or cause blindness if swallowed." The label shall also bear the statement "Cannot be made nonpoisonous."

(5) *Turpentine.* Because turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and

statement of conformance appear with art materials that have been reviewed in accordance with the Commission standard. The Commission interprets this provision to require a conformance statement regardless of the presence of any chronic hazard warnings.

(D) Nothing in this enforcement statement should be deemed to alter any of the requirements of the Federal Hazardous Substances Act ("FHSA"), such as, but not limited to, the requirement that any hazardous substance intended or packaged in a form suitable for household use must be labeled in accordance with section 2(p) of the FHSA.

APPENDIX A TO §1500.14(b)(8)—GUIDELINES FOR A CERTIFYING ORGANIZATION (NOT MANDATORY)

(a) The term "certifying organization," as used in this paragraph, refers to an organization or an institute that, after assuring that all provisions are met, certifies that an art material does conform to the labeling requirements of this practice.

(b) The certifying body may be funded by member manufacturers, but should include users or their representatives, as well as manufacturers' chemists, on its technical and certifying committees.

(c) Representative samples of art materials, labeled as conforming to this section and bought at retail, should be analyzed at random and from time to time by an analytical laboratory to ensure they are the same as the formulation used by the toxicologist(s) for determining labeling requirements.

(d) The methods used by the toxicologist(s) in review and determination of the need and content of precautionary labeling for potentially chronic adverse health effects should be periodically reviewed by an advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board.

(e) In cases where there is disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist's decision can be presented to the advisory board of toxicologists for arbitration.

[38 FR 27012, Sept. 27, 1973, as amended at 41 FR 22934, June 8, 1976; 48 FR 16, Jan. 3, 1983; 53 FR 3018, Feb. 3, 1988; 57 FR 46669, Oct. 9, 1992; 60 FR 8193, Feb. 27, 1995; 61 FR 19629, May 3, 1996; 61 FR 33175, June 26, 1996]

EFFECTIVE DATE NOTES: 1. At 61 FR 19629, May 3, 1996, §1500.14 was amended by redesignating paragraphs (b)(6) (i) and (ii) as (b)(6)(i)(A) and (B), amending newly designated paragraph (b)(6)(i)(A), amending newly designated paragraph (b)(6)(i)(B) by adding "packaged before November 3, 1997" after "charcoal", and adding a new paragraph (b)(6)(ii), effective Nov. 3, 1997.

2. At 61 FR 33175, June 26, 1996, a correction document was published that amended paragraph (b)(6)(i)(A) by adding "packaged before November 3, 1997" after "products" and changing "[insert date that is 18 months after publication]" to read "November 3, 1997," and amending paragraph (b)(6)(ii)(B) by changing "5⅛₆ inches" to read "5 1⅛₆ inches", effective Nov. 3, 1997.

§1500.15 Labeling of fire extinguishers.

When a substance or mixture of substances labeled for use in or as a fire extinguisher produces substances that are toxic within the meaning of §1500.3(c) (1) and (2) when used according to label directions to extinguish a fire, the containers for such substances shall bear the following labeling:

(a) When substances are produced that meet the definition of highly toxic in §1500.3(c)(1), the signal word "Danger" and the statement of hazard "Poisonous gases formed when used to extinguish flame or on contact with heat" are required labeling.

(b) When substances are produced that meet the definition of toxic in §1500.3(c)(2), the signal word "Caution" or "Warning" and the statement of hazard "Dangerous gas formed when used to extinguish flame or on contact with heat" are required labeling.

(c) Regardless of whether paragraph (a) or (b) of this section applies, any substance or mixture of substances labeled for use as a fire extinguisher that, if applied to an electrical fire, would subject the user to the likelihood of electrical shock shall be conspicuously labeled "Caution: Do not use on electrical wires."

(d) The statements specified in paragraphs (a), (b), and (c) of this section shall be in addition to any other that may be required under the act. All such substances or mixtures of substances shall also bear the additional statements "Use in an enclosed place may be fatal" and "Do not enter area until well ventilated and all odor of chemical has disappeared."

appropriate means having an accuracy of ±0.5 pound (±225 grams).

(3) *Testing procedure.* With the test sample fastened in a convenient position, and appropriate clamp shall be attached to the test object or component. A 15-pound ±0.5 pound (6.80-kilogram) direct force shall be evenly applied, within a period of 5 seconds, parallel to the major axis of the test component and maintained for an additional 10 seconds. The tension clamp shall then be removed and a second clamp appropriate for pulling at 90 degrees shall be attached to the test object or component. A 15-pound ±0.5 pound (6.80-kilogram) tensile force shall be evenly applied, within a period of 5 seconds, perpendicularly to the major axis of the test component and maintained for an additional 10 seconds.

(g) *Compression test*—(1) *Application.* Any area on the surface of a toy that is accessible to a child and inaccessible to flat-surface contact during the impact test shall be subject to this test.

(2) *Test apparatus.* The loading device shall be a rigid metal disc 1.125 inches ±0.015 inch (2.86 centimeters) in diameter and 0.375 inch (0.95 centimeter) in thickness. The perimeter of the disc shall be rounded to a radius of 1/32 inch (0.08 centimeter) to eliminate irregular edges. The disc shall be attached to an appropriate compression scale having an accuracy of ±0.5 pound (±225 grams).

(3) *Testing procedure.* The disc shall be positioned so that the contact surface is parallel to the surface under test. A direct force of 30 pounds ±0.5 pound (13.6 kilograms) shall be evenly applied within 5 seconds through the disc. This load shall be maintained for an additional 10 seconds. During the test the toy is to rest on a flat, hard surface in any convenient position.

[40 FR 1486, Jan. 7, 1975; 40 FR 16192, Apr. 10, 1975, as amended by 56 FR 10, Jan. 2, 1991]

§ 1500.81 Exemptions for food, drugs, cosmetics, and fuels.

(a) *Food, drugs, and cosmetics.* Substances subject to the Federal Food, Drug, and Cosmetic Act are exempted by section 2(f)(2) of the act; but where a food, drug, or cosmetic offers a substantial risk of injury or illness from any handling or use that is customary or usual it may be regarded as misbranded under the Federal Food, Drug, and Cosmetic Act because its label fails to reveal material facts with respect to consequences that may result from use of the article (21 U.S.C. 321(n)) when its label fails to bear information to alert the householder to this hazard.

(b) *Fuels.* A substance intended to be used as a fuel is exempt from the requirements of the act when in containers that are intended to be or are installed as part of the heating, cooling, or refrigeration system of a house. A portable container used for delivery or temporary or additional storage, and containing a substance that is a hazardous substance as defined in section 2(f) of the act, is not exempt from the labeling prescribed in section 2(p) of the act, even though it contains a fuel to be used in the heating, cooking, or refrigeration system of a house.

§ 1500.83 Exemption from full labeling and other requirements.

(a) Any person who believes a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full label compliance otherwise applicable under the act, because of the size of the package or because of the minor hazard presented by the substance, or for other good and sufficient reason, may submit to the Commission a request for exemption under section 3(c) of the act, presenting facts in support of the view that full compliance is impracticable or is not necessary for the protection of the public health. The Commission shall determine on the basis of the facts submitted and all other available information whether the requested exemption is consistent with adequate protection of the public health and safety. If the Commission so finds, it shall detail the exemption granted and the reasons therefor by an appropriate order published in the FEDERAL REGISTER.

(b) The Commission may on its own initiative determine on the basis of facts available to it that a particular hazardous substance intended or packaged in a form suitable for use in the household or by children should be exempted from full labeling compliance otherwise applicable under the act because of the size of the package or

the same type size as that required in Table 1 for the other cautionary material which appears elsewhere on the label of a hazardous substance. The size of the cautionary labeling that does not appear on the principal display panel is determined by the area of the panel on which it does appear.

(3) *Type style—proportion.* The ratio of the height of a capital or uppercase letter to its width shall be such that the height of the letter is no more than 3 times its width.

(4) *Signal word and statements of hazard—capital letters.* The signal word, the word "poison" if required instead of a signal word (see §1500.129), and the statement of principal hazard or hazards shall be in capital letters.

(5) *Multiple statement of hazard—type size and style.* All statements of principal hazard or hazards on a label shall appear in the same size and style of type, and shall appear in the same color or have the same degree of boldness.

(6) *Accompanying literature containing directions for use.* Where literature accompanying the package of a hazardous substance has directions for use, written or otherwise, section 2(n) of the Act requires the literature to bear cautionary labeling.

(i) All such cautionary labeling shall be in reasonable proximity to any direction for use and shall be placed together within the same general area.

(ii) The type size of such cautionary labeling shall be reasonably related to the type size of any other printed matter in the accompanying literature and must be in conspicuous and legible type by typography, layout, or color with other printed matter on the label. The signal word and statement of principal hazard or hazards shall appear in capital letters.

(d) *Conspicuousness—contrast.* To satisfy the requirement that cautionary labeling statements appear in conspicuous and legible type which is in contrast by typography, layout, or color with the other printed matter on the label, such statements shall conform to the following requirements:

(1) *Color.* Where color is the primary method used to achieve appropriate contrast, the color of any cautionary labeling statement shall be in sharp contrast with the color of the background upon which such a statement appears. Examples of combinations of colors which may not satisfy the requirement for sharp contrast are: black letters on a dark blue or dark green background, dark red letters on a light red background, light red letters on a reflective silver background, and white letters on a light gray or tan background.

(2) *Interference with conspicuousness—labeling design, vignettes, or other printed material.* For cautionary information appearing on panels other than the principal display panel, the label design, the use of vignettes, or the proximity of other labeling or lettering shall not be such that any cautionary labeling statement is obscured or rendered inconspicuous.

(e) *Collapsible metal tubes.* Collapsible metal tubes containing hazardous substances shall be labeled so that all cautionary labeling required by the Act appears as close to the dispensing end of the container as possible. The placement and conspicuousness of these statements shall conform to the provisions of paragraphs (b), (c), and (d) of this section.

(f) *Unpackaged hazardous substances.* Where practicable, unpackaged hazardous substances intended, or distributed in a form suitable, for use in or around a household or by children shall be labeled so that all items of information required by the Act appear upon the article itself. In instances where this is impracticable (for example, because of the size or nature of the article), the required cautionary labeling must be displayed by means of a tag or other suitable material that is no less than five square inches in area and is securely affixed to the article so that the labeling will remain attached throughout conditions of merchandising and distribution to the ultimate consumer. The placement and conspicuousness of all cautionary labeling appearing on such a tag or material, or on an unpackaged article, shall conform to the provisions of paragraphs (b), (c), and (d) of this section. For the purposes of determining the proper type size to use on a tag or other material, the area of one side of the tag or other

material shall be the area of the principal display panel.

(g) *Exemptions.* All requirements of the Act are satisfied by compliance with this §1500.121. However, exemptions can be granted under section 3(c) of the Act and §1500.83, or under the provisions of another statute should this section be incorporated in regulations under another statute. Section 1500.82 contains the requirements for exemption requests under the Federal Hazardous Substances Act.

(h) *Effective date.* The provisions of this rule apply to hazardous substances bearing labels printed after December 30, 1985. Labels printed prior to the effective date of this rule may be applied until not later than December 28, 1987. This rule applies to all hazardous substances to which labels are applied after December 28, 1987.

[49 FR 50383, Dec. 28, 1984]

§ 1500.122 Deceptive use of disclaimers.

A hazardous substance shall not be deemed to have met the requirements of section 2(p) (1) and (2) of the act (repeated in §1500.3(b)(14) (i) and (ii)) if there appears in or on the label (or in any accompanying literature; words, statements, designs, or other graphic material that in any manner negates or disclaims any of the label statements required by the act; for example, the statement "Harmless" or "Safe around pets" on a toxic or irritant substance.

§ 1500.123 Condensation of label information.

Whenever the statement of the principal hazard or hazards itself provides the precautionary measures to be followed or avoided, a clear statement of the principal hazard will satisfy the requirements of section 2(p)(1) (E) and (F) of the act (repeated in §1500.3(b)(14)(i) (E) and (F)). When the statement of precautionary measures in effect provides instruction for first-aid treatment, the statement of the precautionary measures will satisfy the requirements of section 2(p)(1) (F) and (G) of the act (repeated in §1500.3(b)(14)(i) (F) and (G)).

§ 1500.125 Labeling requirements for accompanying literature.

When any accompanying literature includes or bears any directions for use (by printed word, picture, design, or combination thereof), such placard, pamphlet, booklet, book, sign, or other graphic or visual device shall bear all the information required by section 2(p) of the act (repeated in §1500.3(b)(14)).

§ 1500.126 Substances determined to be "special hazards."

Whenever the Commission determines that for a particular hazardous substance intended or packaged in a form suitable for use in the household or by children, the requirements of section 2(p) of the act (repeated in §1500.3(b)(14)) are not adequate for the protection of the public health and safety because of some special hazard, the Commission, by an appropriate order in the FEDERAL REGISTER, shall specify such reasonable variations or additional label requirements that it finds are necessary for the protection of the public health and safety. Such order shall specify a date that is not less than 90 days after the order is published (unless emergency conditions stated in the order specify an earlier date) after which any such hazardous substance intended, or packaged in a form suitable, for use in the household or by children that fails to bear a label in accordance with such order shall be deemed to be a misbranded hazardous substance.

§ 1500.127 Substances with multiple hazards.

(a) Any article that presents more than one type of hazard (for example, if the article is both toxic and flammable) must be labeled with: An affirmative statement of each such hazard; the precautionary measures describing the action to be followed or avoided for each such hazard; instructions, when necessary or appropriate, for first-aid treatment of persons suffering from the ill effects that may result from each such hazard; instructions for handling and storage of articles that require special care in handling and storage because of more than